IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

CASSANDRA COLVILLE,
an individual

Plaintiff,

vs. Case No.: 4:07-CV-140-SPM

PHARMACIA & UPJOHN
COMPANY LLC, a Florida
Limited Liability Corporation,

Defendant.
_____/

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Defendant's motion for summary judgment (doc. 22) and supporting statement of material facts (doc. 23). Plaintiff has filed a response (doc. 29) and a supporting statement of facts (doc. 30). Plaintiff is a thirty-five year-old woman who has been diagnosed with osteopenia, or loss of bone mineral density. People diagnosed with osteopenia have a strong likelihood of developing osteoporosis. Plaintiff alleges that her development of osteopenia was the direct result of her use of Depo-Provera Contraceptive Injection as a form of birth control, which is manufactured and marketed by Defendant. Plaintiff is now suing Defendant under the theories of negligence and strict liability for their failure to warn patients that extensive use of

Depo-Provera would cause osteopenia. For the reasons set forth below, Defendant's motion for summary judgment will be granted.

I. BACKGROUND

Plaintiff began Depo-Provera as her primary method of birth control in 1995, at the age of twenty-five. Plaintiff used Depo-Provera consistently for eight years, until 2002. Plaintiff initially stopped using Depo-Provera because she wanted to become pregnant. In April 2003, Plaintiff went on a website and read that women taking Depo-Provera should get a DEXA scan. At that time, Plaintiff did not know that the purpose of this scan was to evaluate a person's bone density level. On April 25, 2003, Plaintiff received a DEXA scan. This test showed that Plaintiff had osteopenia in her lumbar spine. The scan was also done on Plaintiff's left hip, but the result was normal.

In early 2004, Plaintiff gave permission for her 16-year-old daughter, Adrianne Oliver, to begin using Depo-Provera as her primary form of birth control. At that time, Plaintiff still had not yet made the connection between taking Depo-Provera and her osteopenia. Plaintiff alleges that neither she nor her doctors were advised that use of the medication for any extensive period of time would lead to the development of osteopenia.

Plaintiff did not have a family history of osteopenia or osteoporosis, nor was Plaintiff in a high-risk category for development of osteoporosis. After Plaintiff's daughter used Depo-Provera for two years, she was diagnosed with

osteopenia. Plaintiff learned that this diagnosis was likely related to her use of Depo-Provera. It was at that time that Plaintiff realized that her own osteopenia was likely the result of her use of Depo-Provera.

On October 29, 1992, the United States Food and Drug administration ("FDA") approved Depo-Provera for use as a safe and effective prescription contraceptive. At that time, Defendant conducted a long-term post-marketing clinical trial to examine the product's effect on bone mineral density. When Depo-Provera was initially approved for use, the FDA approved a package insert for physicians who prescribed Depo-Provera. The package insert contained a "physician information" section and a "patient labeling" section. From 1992 through 2004, the "physicians information section" stated, under the heading "Warnings," information about bone mineral density changes. In substance, the section stated" "Use of Depo-Provera Contraceptive Injection may be considered among the risk factors for development of osteoporosis. The rate of bone loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall."

During the same time period, from 1992 through 2004, the "patient labeling" section had a subsection entitled "Risks of Using Depo-Provera Contraceptive Injection." This subsection stated: "Use of Depo-Provera Contraceptive Injection may be associated with a decrease in the amount of mineral stored in your bones. This could increase your risk of developing bone

fractures. The rate of bone mineral loss is greatest in the early years of Depo-Provera Contraceptive Injection use but, after that, it begins to resemble the normal rate of age related bone loss."

In 2004, as the result of the clinical trial on bone mineral density, together with FDA approval, the package insert was revised to include a black box with bold lettered-font that stated:

> **Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.**
>
> **It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life.**
>
> **Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than two years) only if other birth control methods are inadequate (see WARNINGS).**

Additionally, the revised package insert included a detailed discussion of the results of Defendant's clinical trials that led to the new warning.

Dr. Zinnah Holmes treated Plaintiff from 1994 through 2003. Dr. Holmes is the doctor who prescribed Depo-Provera to Plaintiff. Dr. Holmes testified that the language on the warning label for Depo-Provera was "clear and understandable" language advising physicians that Depo-Provera could be a factor for osteoporosis. Dr. Holmes also testified that she understood that the rate of bone loss was greatest in the early years of use of Depo-Provera and that this warning was adequate to advise her of the risk factors and the greatest period of bone loss

when using Depo-Provera. Dr. Holmes said that she still prescribes Depo-Provera today and that she has not changed the method by which she prescribes it.

In 2005, when Plaintiff relocated to Louisiana, she became a patient of Dr. Rutu Mahajan. At this time, Plaintiff was no longer using Depo-Provera. At her first visit, on August 4, 2005, Dr. Mahajan learned that Plaintiff had been diagnosed with osteopenia by her previous doctor. Dr. Mahajan conducted Plaintiff's second bone density scan on August 5, 2005. He scanned her lumbar spine and left hip. The results were that Plaintiff had osteopenia of the lubar spine. The left hip bone density was normal. On March 9, 2006, Dr. Muhajan reviewed Plaintiff's DEXA scan with her. At that visit, neither Dr. Muhajan nor Plaintiff made a connection between Plaintiff's low bone density and her use of Depo-Provera. Dr. Muhajan also testified that there are no physical symptoms associated with osteopenia and that osteopenia is not an injury, it is "a slow process in the bone which leads to an injury." He also testified that Plaintiff's bone density scan from 2005 showed some improvement from the scan in 2003.

Dr. Leon Cass Terry was selected as Plaintiff's expert in this case.[1] Dr. Terry has experience with synthetic hormones and its effects upon the female body. Prior to rendering an opinion, Dr. Terry reviewed Plaintiff's medical records

[1] There is currently a pending Motion in Limine to exclude the expert opinion of Dr. Terry (doc. 35). After reviewing the motion and the response motion from Plaintiff (doc. 45), this Court finds that Dr. Cass is qualified to testify competently about the matters in this case; 2) his methodology was sufficiently reliable; and 3) his testimony was helpful in assisting this Court determine the relevant facts in issue in this case. Rink v. Cheminova, Inc., 400 F.3d 1286, 1292 (11th Cir. 2005). Accordingly, Defendant's Motion in Limine will be denied.

(including the results of the first two DEXA scans); the court documents filed in this case; research linking Depo-Provera to osteopenia; and research showing the connection between osteopenia and osteoporosis. Dr. Terry testified that Plaintiff's first DEXA scan showed "definitive evidence of osteopenia" in Plaintiff's lumbar spine and left hip. Plaintiff also showed osteopenia in her left femoral neck. The second DEXA scan showed that there was still osteopenia in Plaintiff's lumbar spine. In this scan, there was "no significant loss of bone density in the left hip." Dr. Terry stated that there was "no known genetic history of osteopenia or osteoporosis." Dr. Terry's opinion stated that he believed that the osteopenia was "the direct result of the long-term administration of Depo-Provera for eight years."

In his testimony, Dr. Terry stated that "osteopenia is not a disease, but a term that describes low bone density". Later, he testified that Plaintiff does suffer "some injury as a result of using Depo-Provera" because her DEXA scan showed slight abnormalities. Additionally, Dr. Terry testified that because Plaintiff had not had a DEXA scan prior to taking Depo-Provera, there was no way to know "the extent to which Depo-Provera may have impacted" Plaintiff's bone density. Terry also testified that between Plaintiff's 2005 scan through her 2007 scan, she had improved, especially with regard to her lumbar spine results. Dr. Terry's testimony concluded with the statement that because Plaintiff had not done a baseline DEXA scan, it is possible that Plaintiff could have had low bone density prior to her use of Depo-Provera.

II. STANDARD FOR SUMMARY JUDGMENT

Federal Civil Procedure Rule 56(c) provides for the granting of summary judgment "if the pleadings, depositions, answers to the interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." "Only factual disputes that are material under the substantive law governing the case will preclude entry of summary judgment." Lofton v. Sec'y of the Dep't of Children & Family Servs., 358 F.3d 804, 809 (11th Cir. 2004) (citing Andersen v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Tipton v. Bergrohr GMBH-Siegen, 965 F.2d 994, 998 (11th Cir. 1992)). "An issue of fact is material and genuine if a rational fact-finder could find for the nonmoving party on a fact necessary to establish an element of the claim under applicable substantive law." Ross Neely Sys. v. Occidental Fire & Cas. Co., 196 F.3d 1347, 1350 (11th Cir. 1999).

Initially, the burden is on the moving party to "show, by reference to materials on file, that there are no genuine issues of material fact to be determined at trial." Mullins v. Crowell, 228 F.3d 1305, 1313 (11th Cir. 2000) (citing Clark v. Coats & Clark, Inc., 929 F.2d 604, 608 (11th Cir. 1991)). A common way for the moving party to meet its burden is by demonstrating that the non-moving party cannot show an essential element of his case. Riley v. Newton, 94 F.3d 632, 638-39 (11th Cir. 1996). In determining whether the burden has been met, the court

must "view the evidence and all factual inferences therefrom in the light most favorable to the non-moving party, and resolve all reasonable doubts about the facts in favor of the non-movant." Kingsland v. City of Miami, 382 F.3d 1220, 1226 (11th Cir. 2004) (citations omitted).

A "party opposing a properly-supported motion for summary judgment 'may not rely merely on allegations or denials in its own pleading; rather, its response must--by affidavits or as otherwise provided in this rule--set out specific facts showing a genuine issue for trial.'" Brannon v. Thomas County Jail, 2008 U.S. App. LEXIS 12488, 5-6 (11th Cir. June 9, 2008) (citing Fed. R. Civ. P. 56(e)). "There is a genuine issue of material fact if the nonmoving party has produced evidence such that a reasonable fact-finder could return a verdict in its favor." Brannon at 5-6 (quoting Waddell v. Valley Forge Dental Assocs., Inc., 276 F.3d 1275, 1279 (11th Cir. 2001). "The inquiry is whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Dadeland Depot, Inc. v. St. Paul Fire & Marine Ins. Co., 483 F.3d 1265, 1273 (11th Cir. 2007) (internal quotations omitted).

III. ANALYSIS

Plaintiff's claim falls in two theories of liability: negligence and strict liability. Because this is a diversity action, this Court must apply the substantive laws of Florida. Trumpet Vine Inv., N.V. v. Union Capital Partners I, Inc., 92 F.3d 1110,

1115 (11th Cir. 1996)(citing Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941) (forum state's choice of law rules apply in diversity cases)). The Supreme Court of Florida has chosen to "adopt the doctrine of strict liability as stated by the A.L.I. Restatement (Second) of Torts § 402A" West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976). "Florida courts impose different standards in assessing liability under negligence and strict products liability." Jennings v. Bic Corp., 181 F.3d 1250, 1256 (11th Cir.1999). "In the context of product liability, the basic elements of a negligence cause of action apply: (1) duty of care toward the plaintiff; (2) breach of that duty (or negligence); (3) proximate cause. The plaintiff must also establish that the product was defective or unreasonably dangerous." Marzullo v. Crosman Corp., 289 F.Supp.2d 1337, 1342 (M.D.Fla. 2003).

As to strict liability, a plaintiff must prove that "(1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury." McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1258 (11th Cir. 2002) (citation omitted). "In order to prevail in a products liability action brought under a theory of either strict liability or negligence, a plaintiff must demonstrate that the injuries complained of were caused by a defective product whose defect existed at the time of injury and at the time in which the product left the manufacturer's control." Rodriguez v. National Detroit, Inc., 857 So.2d 199, 201 (Fla. Dist. Ct. App. 2003) (citing Cassisi v. Maytag Co., 396 So.2d

1140, 1143 (Fla. Dist. Ct. App. 1981)). Strict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product. See Valencia v. Sanborn Mfg. Co., No. 04-21416-CIV, 2005 WL 5957819, *12 (S.D. Fla. Aug. 11, 2005); Pinchinat v. Graco Children's Prods., Inc., 390 F. Supp. 2d 1141, 1146-47, 1149 (M.D. Fla. 2005); Timmons v. Purdue Pharma Co., No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, *3 n.6 (M.D. Fla. Feb. 2, 2006); Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990).

Adequacy of Warnings

"A manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug . . . this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs." Buckner v. Allergan Pharms., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. Dist. 1981). "While in many instances the adequacy of warnings concerning drugs is a question of fact, we hold that it can become a question of law where the warning is accurate, clear, and unambiguous." Felix v. Hoffmann-laroche, Inc., 540 So. 2d 102, 105 (Fla. 1989).

The Florida Supreme Court instructs that the adequacy of the warning is determined by whether the "warnings were adequate to warn a physician of the

possibility that [the medicine] might be causing the condition experienced" by the Plaintiff. MacMurdo, 562 So. at 683. This determination must be made through the testimony of an expert. Id. A sister District Court in Florida has held that Defendant pharmaceutical company was entitled to summary judgment because Plaintiff "failed to present an expert witness in support of her claim of inadequate warning." Paparo v. Ortho-McNeil Pharmaceutical, No. 05-81044-CIV-RYSKAMP/VITUNAC, 2007 WL 121149, *4 (S.D. Fla. Jan. 11, 2007) (citing Haggerty v. Upjohn Co., 950 F.Supp. 1160, 1168 (S.D. Fla.1996); MacMurdo, 562 So.2d at 683; and Felix, 540 So.2d at 104)). See also Humphreys v. Gen. Motors Corp., 839 F. Supp. 822, 825 (N.D. Fla. 1993) (defendant "permitted to rely upon the complete absence of proof of an essential element of [p]laintiff[']s case to support its motion for summary judgment"). This Court agrees with that reasoning.

Plaintiff's expert in this case was Dr. Leon Cass Terry, a neurologist. His report consisted "in sum and substance" of all of the opinion that he intended to deliver in this case. Dr. Terry reviewed the medical records of Plaintiff that documented her use of Depo-Provera, research linking Depo-Provera to osteopenia, research showing that osteopenia is likely to develop into osteoporosis, and all of the DEXA bone density scans done on Plaintiff. Dr. Terry testified extensively about the bone density scans done on Plaintiff. However, none of his testimony or his opinion addressed the adequacy of the warnings

provided by Defendant regarding use of Depo-Provera by Plaintiff.

Plaintiff did have testimony from two other doctors, though not presented as experts on the matter of the adequacy of warning labels. One of these doctors, Dr. Holmes specifically stated that the labeling provided by Defendant was an "adequate warning to advise a physician" that Depo-Provera is a risk factor in the development of osteoporosis. The other doctor, Dr. Mahajan, had not reviewed the warnings that were in effect while Plaintiff was taking Depo-Provera. At his deposition, however, Dr. Mahajan confirmed that the warnings did state that Depo-Provera may be considered one of the risk factors for the development of osteoporosis.

Because Depo-Provera's warnings were accurate, clear, and unambiguous, this Court finds that the adequacy of the warning is a question of law. To that end, this Court holds that Depo-Provera's warnings were indeed adequate to warn a physician that use of Depo-Provera may lead to osteoporosis. Accordingly, Plaintiff has not shown the presence of a genuine issue of material fact on this element of her claim.

Causation

In order to establish a prima facie case in this action, Florida law requires Plaintiff to prove by a preponderance of the evidence, with "reasonable medical probability," that Defendant's alleged negligent failure to warn was the proximate cause of Plaintiff's injury. Christopher v. Cutter Lab., 53 F.3d 1184, 1191 (11th Cir.

1995) (citing Reaves v. Armstrong World Industries, Inc., 569 So. 2d 1307, 1309 (Fla. Dist. Ct. App. 1990)). "In other words, plaintiffs must show that is 'more likely than not' that the defendant's act was a substantial factor in bringing about the injury." Christopher, 53 F.3d at 1191 (quoting Gooding v. University Hospital Building, Inc., 445 So. 2d 1015, 1018 (Fla. 1984)). "A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." Reaves, 569 So. 2d at 1309.

Though Plaintiff had no bone density scans prior to her first one on April 25, 2003 that revealed low bone density, given her age and the length of use of Depo-Provera and the testimony of all three of the doctors' testimony, it is very likely that but for Plaintiff's use of Depo-Provera, she would not have been diagnosed with osteopenia. Even without a baseline by which to compare her later bone density scans, given Plaintiff's age and ethnic group, Plaintiff would not have been in a high risk category for the onset of osteopenia.

However, this Court is instructed that this probability and "pure speculation" are not enough. Dr. Holmes, the prescribing physician, testified that she fully understood the warnings and also had prior knowledge of the propensity of Depo-Provera to cause the low bone density. Plaintiff testified that she does not recall reading or discussing the possibility of bone density loss with Dr. Holmes. Dr. Holmes admitted that she does not discuss this particular risk factor with her

patients. Furthermore, Dr. Holmes testified that even after the black box warning was added to the Depo-Provera label, she has continued prescribing Depo-Provera in the same manner, without a specific conversation or warning about the potential for low bone density.

In Felix, an identical factual pattern resulted in a finding that "any inadequacy in the [drug] warning could not have been the proximate cause of the [injury] in this case." 540 So. 2d at 105 (affirming the appellate affirmation of the trial court's entry of summary judgment for defendants). Also, with regard to the liability of the drug manufacturer, the Felix court held that the fact that the physician did not warn the mother about the danger of taking the drug shields the manufacturer from liability because "the drug manufacturer could not be penalized for the failure of the doctor to impart knowledge concerning the dangers of the drug of which the doctor had been warned and was aware." Id. Because Dr. Holmes was aware of the risk factor and did not have a specific conversation with Plaintiff about it, Plaintiff has failed to show that the inadequacy of the manufacturer's warnings was a proximate cause of her osteopenia diagnosis. Therefore, Plaintiff has not demonstrated a genuine issue of material fact for this element of her claim.

Injury

"There is no cognizable cause of action for a mere wrong without damage." Simon v. Bartel, 502 So. 2d 1011, 1012 (Fla. Dist. Ct. App. 1987) Here, no one has definitively testified that Plaintiff's diagnosis of osteopenia is an actual injury.

Specifically, Dr. Mahajan testified that osteopenia is not an injury but a slow process in the bone that could lead to an injury. Dr. Terry testified that osteopenia is not a disease. Additionally, both Drs. Terry and Mahajan allowed for the possibility that Plaintiff's bones could strengthen and the risk of future injury could decrease now that she is no longer taking Depo-Provera.

In a factually analogous case, the District Court of Ohio found that of a doctor's testimony about plaintiff's low bone density was insufficient to demonstrate an injury in the legal sense. Lorenzi v. Pfizer, 519 F. Supp. 2d 742, 751 (N.D. Ohio 2007). In that case, as here, Plaintiff's doctors called osteopenia a diagnosis, not a disease. Therefore, Plaintiff has been unable to establish any current or future injury as a result of her low bone density diagnosis. Accordingly, Plaintiff has not demonstrated a genuine issue of material fact for this third element of her claim.

IV. CONCLUSION

Defendant has successfully shown, by reference to affidavits and depositions on file, that there are no genuine issues of material fact to be determined at trial. Defendant has met its burden by demonstrating that Plaintiff has failed to show all three required elements of her. No reasonable fact-finder would view the evidence in this case and find in favor of Plaintiff. Therefore, Plaintiff is not entitled to relief on her negligence or her strict liability claim and Defendant is entitled to judgment as a matter of law. Accordingly, it is hereby

ORDERED AND ADJUDGED as follows:

1. Plaintiff's motion for extension of time to file a response (doc. 28) is ***granted***.
2. Plaintiff's response in opposition to Defendant's motion for summary judgment (doc. 29) is accepted as timely filed.
3. Defendant motion for summary judgment (doc. 22) is ***granted***.
4. The Clerk shall enter judgment in favor of Defendant and against Plaintiff on all remaining claims.
5. Defendant's Motion in Limine (doc. 34) is hereby ***denied***.
6. Defendant's Daubert Motion (doc. 35) is hereby ***denied***. The Court accepted the expert testimony as reliable and considered this testimony in ruling on the motion for summary judgment.
7. Defendant's Motion for Sanctions (doc. 37) is hereby ***denied***. However, neither party is entitled to attorney fees in connection with this motion.

DONE AND ORDERED this tenth day of July, 2008.

s/ Stephan P. Mickle

Stephan P. Mickle
United States District Judge