

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

KATHLEEN SCHARFF,)	
)	
Plaintiff,)	
v.)	CASE NO. 2:10-CV-220-WKW [WO]
)	
WYETH, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

Plaintiff Kathleen Scharff (“Mrs. Scharff”) claims that she developed breast cancer after taking Prempro, a hormone therapy drug manufactured by Wyeth LLC, Wyeth Pharmaceuticals, Inc., and their predecessors in interest (collectively “Wyeth”).¹ Mrs. Scharff brings suit against Wyeth under Alabama law claiming negligence, wantonness, and liability under the Alabama Extended Manufacturer’s Liability Doctrine (“AEMLD”).²

¹ Mrs. Scharff died of brain cancer on June 11, 2011, during the pendency of this motion. (Doc. # 190.) Wyeth does not dispute the survival of Mrs. Scharff’s claims through a properly appointed personal representative. (Doc. # 198, at 7.) Likewise, Mrs. Scharff’s counsel stipulated that her death raises no new claims in this matter. (Doc. # 198, at 5-6.) However, Mrs. Scharff’s personal representative has not yet been substituted into the case. Given the parties’ understanding about the survival of her claims and the fact that this memorandum opinion is not dispositive of the case, the court does not delay consideration of Defendants’ motion in the absence of her personal representative. The claims herein are referred to as belonging to the late Mrs. Scharff.

² Mrs. Scharff does not contest summary judgment on the other claims in her Amended Complaint.

Before the court is Wyeth's motion for summary judgment and evidentiary submission (Doc. # 76), which is accompanied by a supporting brief (Doc. # 77). Wyeth moves for summary judgment arguing that Mrs. Scharff cannot prove that Prempro was the general or specific cause of her breast cancer, that her claims are barred in whole or in part under the Alabama statute of limitations, and that her products liability claims fail as a matter of law under AEMLD. (Docs. #76-77.) Mrs. Scharff filed a response in opposition (Doc. # 88); Wyeth replied (Doc. # 131); and Mrs. Scharff filed a surreply (Doc. # 139).³ After careful consideration of the arguments of counsel, the applicable law and the record as a whole, the motion is due to be granted in part and ruling is due to be reserved on Wyeth's causation arguments.

II. JURISDICTION AND VENUE

The court properly exercises subject matter jurisdiction over this action, pursuant to 28 U.S.C. § 1332(a) (diversity jurisdiction). Personal jurisdiction and venue are adequately pleaded and not contested.

III. STANDARD OF REVIEW

“Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there

³ Mrs. Scharff moved for leave to file a surreply on May 25, 2011, and the court granted the motion (Doc. # 180).

is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” *Greenberg v. BellSouth Telecomms., Inc.*, 498 F.3d 1258, 1263 (11th Cir. 2007) (*per curiam*) (citation and internal quotation marks omitted); *see* Fed. R. Civ. P. 56(a) (Summary judgment shall be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”). The party moving for summary judgment “always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record, including pleadings, discovery materials and affidavits], which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The movant may meet this burden by presenting evidence indicating there is no dispute of material fact or by showing that the nonmoving party has failed to present evidence in support of some element of its case on which it bears the ultimate burden of proof. *Id.* at 322-24.

If the movant meets its evidentiary burden, the burden shifts to the nonmoving party to establish, with evidence beyond the pleadings, that a genuine issue material to each of its claims for relief exists. Fed. R. Civ. P. 56(e)(3); *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991). What is material is determined by the substantive law applicable to the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,

248 (1986); *see also Lofton v. Sec’y of the Dep’t of Children & Family Servs.*, 358 F.3d 804, 809 (11th Cir. 2004) (“Only factual disputes that are material under the substantive law governing the case will preclude entry of summary judgment.”). Furthermore, “[t]he mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is material to an issue affecting the outcome of the case.” *McCormick v. City of Fort Lauderdale*, 333 F.3d 1234, 1243 (11th Cir. 2003) (*per curiam*) (citation and internal quotation marks omitted).

A genuine issue of material fact exists when the nonmoving party produces evidence that would allow a reasonable fact-finder to return a verdict in its favor. *Greenberg*, 498 F.3d at 1263; *Waddell v. Valley Forge Dental Assocs.*, 276 F.3d 1275, 1279 (11th Cir. 2001). However, if the evidence on which the nonmoving party relies “is merely colorable, or is not significantly probative, summary judgment may be granted.” *Anderson*, 477 U.S. at 242 (citations omitted). “A mere ‘scintilla’ of evidence supporting the [nonmovant’s] position will not suffice; there must be enough of a showing that the [trier of fact] could reasonably find for that party,” *Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir. 1990), and the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts,” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Conclusory allegations based on subjective beliefs are likewise insufficient to create

a genuine issue of material fact and do not suffice to oppose a motion for summary judgment. *Holifield v. Reno*, 115 F.3d 1555, 1564 n.6 (11th Cir. 1997) (*per curiam*) (A plaintiff’s “conclusory assertions . . . in the absence of supporting evidence, are insufficient to withstand summary judgment.”).

Hence, when a plaintiff fails to set forth specific facts supported by appropriate evidence sufficient to establish the existence of an element essential to his case and on which the plaintiff will bear the burden of proof at trial, summary judgment is due to be granted in favor of the moving party. *Celotex Corp.*, 477 U.S. at 323 (“[F]ailure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.”).

Thus, in cases where the evidence before the court is admissible on its face or can be reduced to admissible form and indicates there is no genuine issue of material fact, and where the party moving for summary judgment is entitled to it as a matter of law, summary judgment is proper. *Celotex Corp.*, 477 U.S. at 323-24 (summary judgment appropriate where pleadings, evidentiary materials and affidavits before the court show there is no genuine issue as to a requisite material fact).

IV. FACTS⁴

The pertinent facts surrounding the late Mrs. Scharff's consumption of Prempro, the development of her breast cancer, and her filing of this lawsuit are recounted below.

A. Mrs. Scharff Is Prescribed Prempro

On August 28, 1997, when she was fifty-five years old and a resident of Boaz, Alabama, Mrs. Scharff was prescribed Prempro by her primary physician, Dr. Andrew Reiland. (Doc. # 76, Ex. B, at 27 (“Scharff Dep. Vol. I”); Doc. # 88, Ex. A; Doc. # 88, Ex. B, at 4, 52 (“MDL Fact Sheet”).) Dr. Reiland prescribed Prempro for Mrs. Scharff because of her menopausal symptoms, including extreme hot flashes and extreme vaginal dryness. (Doc. # 76, Ex. C, at 121-22 (“Dr. Reiland Dep.”); Doc. # 76, Ex. A, at 17-18 (“Scharff Dep. Vol. II”); Doc. # 88, Ex. A.) Dr. Reiland did not prescribe Prempro to Mrs. Scharff to prevent osteoporosis, Alzheimer's disease, or for heart protection, nor did he tell her of such benefits. (Scharff Dep. Vol. II, at 21-23.) At the time of her prescription, Mrs. Scharff did not recall receiving a book, brochure, or other information about menopause from Dr. Reiland. (Scharff Dep. Vol. II, at 21.)

⁴ The actual facts may be different than those stated here. *See Lee v. Ferraro*, 284 F.3d 1188, 1190 (11th Cir. 2002) (“[F]acts, as accepted at the summary judgment stage of the proceedings, may not be the actual facts of the case. Nevertheless, for summary judgment purposes, [the] analysis must begin with a description of the facts in the light most favorable to the plaintiff.”) (citation and internal quotation marks omitted).

Mrs. Scharff relied solely on Dr. Reiland's advice in deciding to take Prempro, and she did not recall seeing any advertisements for Prempro before or during the period she took Prempro. (Scharff Dep. Vol. I, at 81; Scharff Dep. Vol II, at 19, 78.) Mrs. Scharff recalled that her Prempro prescription package probably included the Patient Information Insert, that she probably glanced at it, but that she did not read it. (Scharff Dep. Vol. I, at 77, 138-39; Scharff Dep. Vol. II, at 26.)

i. Background on Prempro

Prempro comes in pill form and combines Premarin, conjugated estrogens, and Medroxyprogesterone acetate, a synthetic progestin. (Doc. # 88, Ex. C, at 3120 (1998 Physicians' Desk Reference ("1998 PDR")).) At the time of Ms. Scharff's prescription, Prempro was manufactured Ayerst Laboratories, Inc., which was then owned by Wyeth-Ayerst, a predecessor in interest to Wyeth, LLC. (Doc. # 88, at 7; 1998 PDR, at 3124.) In 1994, the Food and Drug Administration ("FDA") approved Prempro for the treatment of menopausal symptoms and for the prevention of osteoporosis. (Doc. # 76, Ex. E ("1994 FDA Approval").) The language of Prempro's 1998 Patient Information Insert is found in the 1998 PDR, which the parties agree contains substantially the same language as the 1997 PDR and Patient Information Insert. (Doc. # 88, at 8 & n.3; Doc. # 77, at 4 n.1) Prempro's Patient Information Insert, as reproduced in the 1998 PDR, included the following warning:

WARNINGS

ALL WARNINGS BELOW PERTAIN TO THE USE OF THIS COMBINATION PRODUCT.

Based on experience with estrogens and/or progestins:

1. Induction of malignant neoplasms

Breast Cancer. Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship. In a one year clinical trial of PREMPRO, PREMPHASE®, and Premarin alone, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments, while no new cases were detected among 347 women who received Premarin alone. The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population.

In the three year clinical Postmenopausal Estrogen Progestin Intervention (PEPI) trial of 875 women to assess differences among placebo, unopposed Premarin, and three different combination hormone therapy regimens, one (1) new case of breast cancer was detected in the placebo group (n=174), one [(1)] in the Premarin alone group (n=175), none in the continuous Premarin plus continuous medroxyprogesterone acetate group (n=174), and two (2) in the continuous Premarin plus cyclic medroxyprogesterone acetate group (n=174). Women on hormone replacement therapy should have regular breast examinations and should be instructed in breast self-examination, and women over the age of 50 should have regular mammograms.

(1998 PDR at 3121-22; Doc. # 88, at 7-8.) It also warned that:

RISKS OF ESTROGENS AND/OR PROGESTINS

...

Cancer of the Breast. Most studies have not shown a higher risk of breast cancer in women who have ever used estrogens. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for long periods of time (especially more than 10

years), or who used high doses for shorter time periods. The effects of added progestin on the risk of breast cancer are unknown. Some studies have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. Others have not. Regular breast examinations by a health professional and monthly self-examination are recommended for all women. Regular mammograms are recommended for all women over 50 years of age.

(1998 PDR at 3124; Doc. # 88, at 8.)

ii. Dr. Reiland's Knowledge Concerning Prempro

In 1997, when Dr. Reiland prescribed Prempro to Mrs. Scharff, he had background knowledge of the risk of breast cancer associated with hormone replacement therapy. (Dr. Reiland Dep. 39.) Dr. Reiland would discuss this breast cancer risk with his patients when prescribing hormone replacement therapy, but he “would always say that the majority of the studies seemed to be reassuring.” (Dr. Reiland Dep. 108-09.) Dr. Reiland recognized in 1997 that there was conflicting literature regarding the association of breast cancer and hormone replacement therapies. (Dr. Reiland Dep. 39-40.) He also indicated that he was a little skeptical of the 1997/1998 PDR language stating that “the majority of studies have not shown an association [with a higher risk of breast cancer] in women who have ever used [estrogen replacement therapy],” because some of those studies may have been inaccurate. (Dr. Reiland Dep. 39.) Dr. Reiland also testified that the 1998 PDR label referencing the Postmenopausal Estrogen Progestin Intervention (“PEPI”) trial did not indicate a greater chance of breast cancer associated with hormone replacement

therapy relative to the background population, and that he found this to be “somewhat reassuring.” (Dr. Reiland Dep. 40-41, 43-44.) When asked about Prempro’s 2007 PDR label, Dr. Reiland found its black box label to be comparably stronger than the 1997-99 PDR labels for Prempro. (Dr. Reiland Dep. 47-50.) He also stated that he wished that he had had that information available in 1997, and that he would have passed that information along to Mrs. Scharff. (Dr. Reiland Dep. 47-50.) He also believed that if Wyeth’s sales representatives had the 2007 label information in 1997 or 1998, they would have passed it along to him. (Dr. Reiland Dep. 50-51.) Dr. Reiland agreed that accurate information about a drug was important to a doctor’s risk/benefit analysis. (Dr. Reiland Dep. 63-65.) If a drug’s risks outweighed its benefits, Dr. Reiland said that he generally would not have prescribed it, but ultimately the decision to take a drug would be up to the patient and he would pass along all the available information to the patient. (Dr. Reiland Dep. 65-66.)

Dr. Reiland’s decision to prescribe Prempro to Mrs. Scharff was not affected by any Wyeth sales representatives’ calls or promotional materials, though he did receive sales calls from Wyeth sales representatives before, during, and after his prescription of Prempro to Mrs. Scharff. (Dr. Reiland Dep, 21-22, 142; Doc. # 88, Ex. J.) According to Wyeth’s sales records, Dr. Reiland met with Susan Hendrick, a Wyeth sales representative, on July 1, 1997, and she reported in her notes, “[Dr.

Reiland] has used the Premphase and said that we need to have more info on it to give to the patient, I gave him the tear-off sheets and left videos and pamphlets for his patients. We really do need more give-aways for Premphase for these docs that are using [sic] it.” (Doc. # 88, Ex. J.) On November 25, 1997, she reported that, “[Dr. Reiland] said that he loves the XXXXXXXX and hasn’t heard back from any girls he has put it on[.] Liked the XXX and said that it was about time that we made it once a day - much easier[.] Premarin and lowering lipids - he heartily agreed[.]” (Doc. # 88, Ex. J.)

B. Mrs. Scharff’s Breast Cancer Diagnosis and Treatment

Ms. Scharff took Prempro as prescribed from August 28, 1997, to January 26, 1999. (MDL Fact Sheet at 4; Scharff Dep. Vol. II, at 24.) Prempro was the only hormone replacement drug that Mrs. Scharff ever took, and Dr. Reiland was the only doctor who prescribed it for her. (Scharff Dep. Vol. II, at 72.) Prempro alleviated Mrs. Scharff’s menopausal symptoms, but those symptoms returned once she stopped taking the drug. (Scharff Dep. Vol. II, at 72-73.) On September 24, 1998, approximately thirteen months after she began taking Prempro, Mrs. Scharff visited Dr. Reiland and reported that she felt a lump in one of her breasts. (Dr. Reiland Dep. 130; Scharff Dep. Vol. I, at 39.) Dr. Reiland immediately referred Mrs. Scharff to Dr. Naughton, a local surgeon, for a follow-up on the lump in her breast. (Scharff. Dep.

Vol. I, at 39.) On September 25, 1998, she received a mammogram from Dr. Reiland, and Mrs. Scharff visited Dr. Naughton. (Dr. Reiland Dep. 131; Scharff Dep. Vol. I, at 39, 42.) According to Mrs. Scharff, Dr. Naughton told her that, “Let’s just watch it. It’s probably nothing.” (Scharff. Dep. Vol. II, at 32.) Dr. Naughton recalled that he recommended a short follow-up and a re-evaluation. (Doc. # 88, Ex. L, at 14 (“Dr. Naughton Dep.”).)

In early January 1999, Dr. Naughton called Mrs. Scharff and told her, “we have to have that checked.” (Scharff Dep. Vol. II, at 32-33.) On January 12, 1999, Mrs. Scharff visited Dr. Naughton, who performed a biopsy on the lump in her breast and sent the biopsy off for analysis. (Dr. Reiland Dep. 132; Scharff Dep. Vol. II, at 32-33; Doc. # 76, Ex. H (“Dr. Naughton January 13, 1999 Record”).) On January 13, 1999, the Gadsden Regional Medical Center Pathology Department issued a pathology report diagnosing her breast tissue biopsy as: “BREAST, RIGHT, SURGICAL BIOPSY: INVASIVE MODERATELY DIFFERENTIATED DUCTAL CARCINOMA”⁵ (Dr. Naughton January 13, 1999 Record.) Plaintiff’s evidence is that Mrs. Scharff was told of her breast cancer diagnosis on January 18, 1999 by Dr. Naughton. (Doc. # 88, at 19; Doc. # 88, Ex. M.) At that same time, Dr. Naughton

⁵ Whether Mrs. Scharff’s breast cancer was ductal or tubular-lobular is hotly contested. The initial report of ductal cancer is referenced here as it pertains to the date her breast cancer was diagnosed, but the court does not draw the factual conclusion that her breast cancer was ductal. Such a factual conclusion is unnecessary to this memorandum opinion.

also told her to stop taking Prempro, and she did.⁶ (Scharff Dep. Vol. I, at 71.) Mrs. Scharff did not ask Dr. Naughton why he was instructing her to stop taking Prempro, nor did Dr. Naughton recall Mrs. Scharff asking him if hormone therapy caused her breast cancer. (Scharff Dep. Vol. II, at 80, 86-87; Dr. Naughton Dep. 32-33.) There is also no evidence in the record that she asked Dr. Reiland about the cause of her breast cancer.

After consulting with a radiation oncologist, Mrs. Scharff elected to have a radical mastectomy done on her right breast. (Dr. Naughton Dep. 31-32; Scharff Dep. Vol. II, at 34.) Mrs. Scharff's mastectomy of her right breast was performed by Dr. Naughton on January 26, 1999.⁷ (Dr. Reiland Dep. 134; Dr. Naughton Dep. 36-38.) On February 2, 1999, Mrs. Scharff's breast cancer was diagnosed as both ER+ (estrogen receptor positive) and PR+ (progesterin receptor positive). (Doc. # 88, Ex. O ("February 2, 1999 Lab Report").)

⁶ The MDL fact sheet reflects that Mrs. Scharff ceased taking Prempro on January 26, 1999, over a week after she was told of her cancer diagnosis. (MDL Fact Sheet 4.) However, the MDL fact sheet also reflects that "[Dr. Naughton] instructed plaintiff to discontinue hormone therapy" on January 11, 1999. (MDL fact Sheet 54.) These factual inconsistencies are immaterial here.

⁷ Mrs. Scharff later elected to have a mastectomy performed on her left breast due to shoulder pain and general discomfort, and to avoid continued consumption of the drug tamoxifen. (Scharff Dep. Vol. I, at 61-62; Scharff Dep. Vol. II, at 35-36, 79-80.)

C. The Women’s Health Initiative, Prempro, and Mrs. Scharff

The National Institutes of Health published its report of the Women’s Health Initiative (“WHI”) on July 9, 2002. (Doc. # 88, Ex. P (“WHI Press Release”).) A brief description of the WHI study follows:

The estrogen plus progestin trial of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer. The study did not address the short-term risks and benefits of hormones for the treatment of menopausal symptoms.

(WHI Press Release 2.) The WHI Press Release also stated that “[t]he National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) [] stopped early a major clinical trial of the risks and benefits of combined estrogen and progestin in healthy menopausal women due to an increased risk of invasive breast cancer.” (WHI Press Release 1.) The study was stopped after an average follow-up period of 5.2 years. (WHI Press Release 1.) The WHI Press Release explained that the estrogen plus progestin group in the study experienced a 26 percent increase in breast cancer compared to the placebo group. (WHI Press Release 4.)

The publication of the WHI study in July 2002 garnered a great deal of media attention. (*See, e.g.*, Dr. Reiland Dep. 68.) Dr. Reiland testified that the study found that there was an increased incidence of breast cancer in the study population, which

had a profound impact on his understanding of the risks and benefits involved in hormone replacement therapy. (Dr. Reiland Dep. 68-69.) It was not, however, the first time he had been made aware of the increased incidence of breast cancer associated with hormone replacement therapy. (Dr. Reiland Dep. 71.) He noted a change in the labeling of Prempro after the WHI study was published. (Dr. Reiland Dep. 72-73.)

Mrs. Scharff did not recall the publication of the WHI study or reading anything about the findings of that study. (Scharff Dep. Vol. II, at 39-40.) However, Mrs. Scharff did begin to connect her breast cancer to her consumption of Prempro sometime between 2003 and 2005 when she “started seeing more articles in the paper and stuff like that.” (Scharff Dep. Vol. II, at 39, 78.) During that period, she collected newspaper clippings of articles discussing the association of hormone replacement therapy and breast cancer. (Scharff Dep. Vol. II, at 39-40.)

D. Procedural Posture of Mrs. Scharff’s Suit

The procedural history of Mrs. Scharff’s present action is pertinent to Wyeth’s argument that Alabama’s statute of limitations precludes her claims. Mrs. Scharff originally filed her claims as a part of a multi-plaintiff suit (the “multi-plaintiff suit”) in the District Court of Hennepin County, Minnesota, which was served on Wyeth on January 12, 2005. (Doc. # 88, Ex. Q, at 2.) On February 1, 2005, that suit was

removed by Wyeth to the United States District Court for the District of Minnesota. (Doc. # 88, Ex. Q, at 1.) On April 4, 2005, the multi-plaintiff suit, including Mrs. Scharff's cause, was transferred to the Multi-District Litigation ("MDL") Docket No. 1507: *In re Prempro Products Liability Litigation* ("*In re Prempro*") before District Judge William R. Wilson, Jr. of the Eastern District of Arkansas. See *Concetta Alsin v. Wyeth*, Case No. 0:05-CV-227-JRT-JGL (D. Minn. 2005) (Doc. # 15).

Mrs. Scharff remained a plaintiff in the *In re Prempro* MDL until February 12, 2010, when Judge Wilson issued an Order severing all plaintiffs, except Concetta Alsin, from the multi-plaintiff suit for violation of the Federal Rules of Civil Procedure and his August 2004 Order directing attorneys to "avoid filing complaints joining unrelated individuals as parties-plaintiff" (Doc. # 76, Ex. I, at 1 n.1.) All plaintiffs, *other* than Mrs. Scharff, were given thirty days to file a new individual civil action in an appropriate court for transfer back to MDL No. 1507. (Doc. # 76, Ex. I.) Judge Wilson stated that Mrs. Scharff, as an *in extremis* plaintiff alleging injuries against only Wyeth and Pfizer, "no longer need[ed] to be consolidated in MDL No. 1507." (Doc. # 76, Ex. I, at 2.) Therefore, he ordered that,

[i]f Plaintiff Scharff commences a *new* action, she must promptly file a statement with that court indicating that the case is not appropriate for transfer to MDL No. 1507, because: (1) Plaintiff was previously a party in that multidistrict litigation (specifically, in Case No. 4:05CV00596-WRW); and (2) the presiding judge in MDL No. 1507 determined that

the continued inclusion of Plaintiff's claims in the multidistrict litigation was no longer warranted.

(Doc. # 76, Ex. I, at 2-3 (emphasis added).) As to the effect of his Order on the statute of limitations and other time-bar laws, Judge Wilson explained,

For the application of statutes of limitations, laches, or other time-bar laws, the filing date of a *newly filed action* pursuant to this Order will be deemed to relate back to the date that the dropped plaintiff originally filed her complaint – insofar as the new complaint alleges only the claims alleged in the original complaint and joins only the defendants named (or fewer) in the original complaint, or the successors of such original defendants.

(Doc. # 76, Ex. I, at 2 (emphasis added).)

Mrs. Scharff filed the instant action in this court on March 11, 2010, within thirty days of the February 12, 2010 Order. (Compl.) It is undisputed by the parties that the Complaint (Compl.) and the Amended Complaint (Am. Compl.) complied with Judge Wilson's February 12, 2010 Order, and that Mrs. Scharff's claims, for the purposes of timeliness, relate back to the date the multi-plaintiff suit was filed.

E. Mrs. Scharff's Claims

Mrs. Scharff pursues the following claims: (1) common law negligence (Count I); (2) that Prempro constitutes a defective product under the AEMLD (Count II); and (3) that Prempro was defectively marketed and contained inadequate warnings in

violation of the AEMLD (Count III).⁸ (*See* Am. Compl. 25-32; Doc. # 88, at 35-41.)

The parties dispute whether these counts each include a wantonness claim, an issue addressed in Part V.

Mrs. Scharff seeks unspecified general damages, damages for physical pain and suffering, exemplary damages, reasonable attorney's fees, costs, and pre- and post-judgment interest. She also demands a jury trial.

V. DISCUSSION

Wyeth argues summary judgment is appropriate because (1) Mrs. Scharff's claims are time-barred under applicable Alabama law; (2) Mrs. Scharff lacks admissible evidence that Prempro caused her injuries; (3) Mrs. Scharff's defective design and defective manufacture claims in Count II fail as a matter of law under Alabama law; and (4) Mrs. Scharff's defective marketing claim in Count III fails as a matter of law under Alabama law. (Doc. # 77, at 9, 13, 17, and 20.) Because the statute of limitations stands as a threshold defense to all of Mrs. Scharff's claims, Part A addresses that issue. Summary judgment is due to be granted in part because Mrs. Scharff's negligence and AEMLD claims are time-barred. Finding that only Mrs. Scharff's common law wantonness claims survive the statute of limitations at this

⁸ Mrs. Scharff concedes that summary judgment is due to be entered on Count IV (Breach of Express Warranty), Count V (Negligent Misrepresentations), Count VI (Fraud), and Count VII (Alter Ego / Corporate Liability / Civil Conspiracy). (Doc. # 88, at 14.) Thus, like Mrs. Scharff's response (Doc. # 88, at 14), this opinion does not further address those claims.

stage, Part B briefly discusses why ruling is reserved on Wyeth's motion for summary judgment on general and specific causation.⁹

A. The Statute of Limitations

The parties do not dispute that Mrs. Scharff's tort claims proceed under Alabama law; however they clash over which state's law supplies the applicable statute of limitations. Wyeth argues that all of Mrs. Scharff's claims are barred under Alabama's two-year statute of limitations for negligence and products liability claims. (Doc. # 77, at 13.) Mrs. Scharff contends that her suit is timely under Minnesota's statute of limitations and its "discovery rule." (Doc. # 88, at 19.) She argues that Minnesota's statute of limitations applies to her case because she filed her original lawsuit in Minnesota and the later actions of the MDL court in severing her cause of action "are akin to a transfer under [28 U.S.C. § 1404(a)] instead of a transfer under [28 U.S.C.] § 1406(a)." (Doc. # 88, at 23.) Alternatively, Mrs. Scharff argues that her claims are timely under Alabama law because Wyeth did not seek summary judgment on her alleged wantonness claims that carry a six-year statute of limitations in Alabama. (Doc. # 88, at 23-27.) She also argues that the statute of limitations was tolled on her negligence and products liability claims by Wyeth's alleged fraudulent

⁹ Wyeth's AEMLD arguments are moot because Mrs. Scharff's AEMLD claims are barred by the statute of limitations.

concealment and a 2003 Alabama class action against Wyeth. (Doc. # 88, at 27-35.) Wyeth replies that Alabama law applies, Mrs. Scharff did not plead wantonness claims in her Amended Complaint, and tolling does not render her claims timely. (Doc. # 131, at 2-20.)

i. Choice of Law

“Federal courts sitting in diversity apply the forum state’s choice-of-law rules.” *Boardman Petroleum, Inc. v. Federated Mut. Ins. Co.*, 135 F.3d 750, 752 (11th Cir. 1998). “It is also true, however, that when a case is transferred from one forum to another, the transferor court’s choice-of-law rules apply to the transferred case even after the transfer occurs.” *Id.* (citing 28 U.S.C. § 1404(a)). Contrary to Mrs. Scharff’s arguments, however, this is not a transferred case. Judge Wilson’s February 12, 2010 Order clearly stated that Mrs. Scharff was dropped from the multi-plaintiff suit pursuant to Rule 21 of the Federal Rules of Civil Procedure. (Doc. # 76, Ex. I, at 1.) Judge Wilson advised Mrs. Scharff and the other dropped plaintiffs that each had thirty-days following severance to “file *new*, individual complaints in a *proper venue*.” (Doc. # 76, Ex. I, at 1 (emphasis added).) Further, Judge Wilson found that as an *in extremis* plaintiff, Mrs. Scharff was no longer to be consolidated with the MDL, and that if she “commence[d] a *new* action,” her case should not be transferred to the MDL. (Doc. # 76, Ex. I, at 2-3 (emphasis added).) Mrs. Scharff did just that. She

timely filed a new action in the Middle District of Alabama in accordance with Judge Wilson's February, 12, 2010 Order.

Mrs. Scharff's reliance on *Fleeger v. Wyeth*, 771 N.W. 2d 524 (Minn. 2009) for the proposition that the Minnesota statute of limitations controls her case is misplaced. In *Fleeger*, the *In re Prempro* MDL court certified a question to the Minnesota Supreme Court asking whether the Minnesota statute of limitations controlled an action that was transferred to the MDL, but was originally filed in Minnesota by a Pennsylvania resident against non-Minnesota resident defendants complaining of events that occurred outside of Minnesota. The Minnesota Supreme Court determined that the Minnesota statute of limitations did apply in that case. *Fleeger* is distinguishable from this case because, unlike that plaintiff, Mrs. Scharff was dropped from the predicate multi-plaintiff suit that was filed in Minnesota in 2005 and later transferred to the MDL. Her case was not transferred to this court. Rather, Mrs. Scharff voluntarily chose this forum and filed a new action, thus availing herself of Alabama's choice of law doctrine.

Under Alabama law, the doctrine of *lex loci delicti* applies to tort claims, meaning that the law of the state in which the injury occurred governs the substantive rights of an injured party, while the procedural law is supplied by the forum state. *Randolph v. Tenn. Valley Auth.*, 792 F. Supp. 1221, 1222 (N.D. Ala. 1992); *Fitts v.*

Minn. Min. & Mfg. Co., 581 So. 2d 819, 820 (Ala. 1991).¹⁰ The Alabama statutes of limitation for negligence, wantonness, and AEMLD claims are procedural. *See, e.g., Etheridge v. Genie Indus., Inc.*, 632 So. 2d 1324, 1326-27 (Ala. 1994) (A statute of limitations that places a time limit on filing an action is a procedural statute that affects only a plaintiff's remedy.). Because she filed her new lawsuit in Alabama, Alabama's statute of limitations controls.

ii. Accrual of Mrs. Scharff's claims

“All civil actions must be commenced after the cause of action has accrued within the period prescribed in this article and not afterwards, unless otherwise specifically provided for in the code.” Ala. Code § 6-2-30(a). “A cause of action ‘accrues’ as soon as the party in whose favor it arises is entitled to maintain an action thereon.” *Smith v. Medtronic, Inc.*, 607 So. 2d 156, 159 (Ala. 1992). A tort claim accrues “only when the force wrongfully put in motion produces injury, the invasion of personal or property rights occurring at that time.” *Stephens v. Creel*, 429 So. 2d 278, 281 (Ala. 1983) (quoting 51 Am. Jur. 2d *Limitation of Actions* § 135 (1970)). “At the time of the first legal injury, the period of limitations begins to run, whether or not the full amount of damages is apparent.” *Medtronic*, 607 So. 2d at 159.

¹⁰ There is also no dispute that Mrs. Scharff's injuries occurred in Alabama.

Mrs. Scharff took Prempro from August 28, 1997, to January 26, 1999. Mrs. Scharff argues that her cause of action accrued when her breast cancer was diagnosed in a lab report on January 13, 1999, or when she was notified of the result on January 18, 1999. (Doc. # 88, at 19.) Wyeth does not dispute Mrs. Scharff's contention accepting, at this stage, that Mrs. Scharff's cause of action accrued no later than January 1999, when she was diagnosed with breast cancer and underwent a mastectomy. (Doc. # 77, at 14; Doc. # 131, at 12.) As will become clear, it is unnecessary to choose between the two January dates. Viewing the facts in the light most favorable to Mrs. Scharff, the court assumes, without deciding, that her claim accrued on January 18, 1999.

iii. Alabama's Two-Year Statute of Limitations

Mrs. Scharff's negligence and AEMLD claims are governed by Alabama's two-year statute of limitations. Ala. Code § 6-2-38(1); *Ex parte Capstone Building Corp.*, No. 1090966, 2011 WL 2164027, at *3 (Ala. June 3, 2011); *Locke v. Ansell, Inc.*, 899 So. 2d 250, 251 n.2 (Ala. Oct. 8, 2004) (decided after *McKenzie v. Killian*, 887 So. 2d 861 (Ala. Mar. 5, 2004)); *Medtronic*, 607 So. 2d at 159 (An action alleging "liability under the AEMLD must be brought within two years after the cause of action accrued."). Given the January 18, 1999 accrual date of Mrs. Scharff's claims, she had until January 18, 2001, to file her negligence and AEMLD claims against Wyeth.

However, Mrs. Scharff did not file the multi-plaintiff suit until January 12, 2005. Thus, Mrs. Scharff must establish sufficient tolling of the statute of limitations to make up for her nearly four-year delay in filing her claims.

iv. Tolling of the Two-Year Statute of Limitations

Mrs. Scharff advances two tolling arguments that she claims render her January 2005 suit timely despite Wyeth's statute of limitations defense. First, she argues that Wyeth fraudulently concealed the risks of Prempro from January 1999 until the publication of the WHI report on July 9, 2002, thus tolling the statute of limitations until July 9, 2004, under Alabama Code § 6-2-3. (Doc. # 88, at 28-29.) Second, she argues that the statute of limitations was tolled from April 14, 2003, until her filing of the multi-plaintiff suit on January 15, 2005, by an April 14, 2003 Alabama class action suit asserting claims against Wyeth for injuries caused by Prempro. (Doc. # 88, at 31-35.) Wyeth argues that Mrs. Scharff must establish that both of these tolling doctrines apply in order to render her claims timely, and this she cannot do. (Doc. # 131, at 7.) Because Mrs. Scharff has failed to raise genuine issues of material fact sufficient to invoke fraudulent concealment tolling, the court need not address her class action tolling arguments.

Alabama Code § 6-2-3 provides the statutory basis for tolling by fraudulent concealment. Alabama Code § 6-2-3 states,

In actions seeking relief on the ground of fraud where the statute has created a bar, the claim must not be considered as having accrued until the discovery by the aggrieved party of the fact constituting the fraud, after which he must have two years within which to prosecute his action.

Section 6-2-3 is not limited to fraud causes of action, however, and “may be applied to other torts not arising in fraud in appropriate cases, and applies to a fraudulent concealment of the existence of a cause of action.” *DGB, LLC v. Hinds*, 55 So. 3d 218, 224 (Ala. 2010) (internal quotation marks and citation omitted); *see also Hudson v. Moore*, 194 So. 147, 149 (Ala. 1940) (The predecessor to Alabama Code § 6-2-3 also applied “to a fraudulent concealment of the existence of a cause of action from the party in whose favor the cause of action exists. A party cannot profit by his own wrong in concealing a cause of action against himself until barred by limitation. The statute of limitations cannot be converted into an instrument of fraud.”), *abrogated on other grounds by Ex parte Sonnier*, 707 So. 2d 635, 638 (Ala. 1997). “A plaintiff using the tolling statute must allege, or on summary judgment establish, prima facie facts which show that the defendant fraudulently prevented discovery of the wrongful act on which the action is based.” *Sellers v. A.H. Robins Co., Inc.*, 715 F.2d 1559, 1561 (11th Cir. 1983) (citing *Hudson*, 194 So. at 147). However, § 6-2-3 does not create a “discovery” rule for tolling the statute of limitations, because “in the absence of fraudulent concealment, the cause of action begins to run when it accrues, whether or not the party has discovered the tort or injury.” *Id.* at 1561 n.** (citing *Garrett v.*

Raytheon Co., Inc., 368 So. 2d 516, 519 (Ala. 1979), *overruled on other grounds by Griffin v. Unocal Corp.*, 990 So. 2d 291, 293 (Ala. 2008)).

If a plaintiff establishes fraudulent concealment tolling, “the limitations period commences once the fraud is readily discoverable or the potential plaintiff is on notice that a fraud may have been perpetrated.” *Lampliter Dinner Theater, Inc. v. Liberty Mut. Ins. Co.*, 792 F.2d 1036, 1043 (11th Cir. 1986) (citing *Johnson v. Shenandoah Life Ins. Co.*, 281 So. 2d 636, 642-43 (Ala. 1973)). “Facts that would provoke a reasonable person’s inquiry and lead to a discovery of the fraud commence the limitations period.” *Id.* (citing *Butler v. Guar. Sav. & Loan Ass’n*, 37 So. 2d 638 (Ala. 1948)).

In order to establish prima facie facts of fraudulent concealment of the existence of a cause of action, Mrs. Scharff must produce evidence sufficient to create a genuine issue of material fact: “(1) that the defendant had a duty to disclose a material fact; (2) that the defendant either failed to disclose or concealed that material fact; (3) that the defendant’s failure to disclose or [its] concealment of that material fact induced the plaintiff to act or to refrain from acting; and (4) that the plaintiff suffered damage as a result of [its] action, or inaction, induced by the defendant’s failure to disclose or [its] concealment of the material fact.” *Soniat v. Johnson-Rast & Hays*, 626 So. 2d 1256, 1258-59 (Ala. 1993); *see also Payton v. Monsanto Co.*, 801 So. 2d 829, 834

(Ala. 2001). However, a breach of the duty to warn by a manufacturer does not toll the statute of limitations under Alabama law, because “a mere failure or refusal to warn, without more, while actionable, does not rise to the level of fraudulent concealment [that tolls the statute of limitations].” *Cazales v. Johns-Manville Sales Corp.*, 435 So. 2d 55, 58 (Ala. 1983).

Mrs. Scharff argues that she is due fraudulent concealment tolling because: (1) she pleaded that she did not discover that Prempro caused her breast cancer until after July 9, 2002, and she testified that she did not connect her use of Prempro to her breast cancer until sometime in 2003 or 2004 (Doc. # 88, at 29); (2) she pleaded the facts and circumstances of Defendants’ actions to conceal the cause of action (Doc. # 88, at 29); (3) she pleaded that Wyeth’s fraudulent concealment of facts prevented her from discovering the fact that Prempro caused her breast cancer (Doc. # 88, at 31); (4) another plaintiff, not a party to this action, addressed Wyeth’s alleged fraudulent concealment in opposition to a motion for summary judgment in a Texas state court, which Mrs. Scharff asks the court to incorporate by reference (Doc. # 88, at 29-30 n.29); (5) three letters sent by Wyeth representatives in July 2000 provide proof of Wyeth’s fraudulent concealment (Doc. # 88, at 30); and (6) she has produced evidence that the language of the patient insert and the Physician’s Desk Reference failed to warn her and her doctor of the dangers of Prempro (Doc. # 88, at 31). Wyeth argues

that Mrs. Scharff has failed to produce evidence of any misrepresentations by Wyeth that prevented her from discovering her cause of action, that there is no evidence that Mrs. Scharff sought to discover the cause of her breast cancer during this period, and that any alleged failure to warn by Wyeth is insufficient for fraudulent concealment. (Doc. # 77, at 16; Doc. # 88, at 8-11). Wyeth has the better argument.

Analysis begins with Mrs. Scharff's arguments concerning the sufficiency of her pleadings, then turns to the relevance of Mrs. Scharff's evidence that Wyeth fraudulently concealed her cause of action, and concludes with Mrs. Scharff's lack of evidence of reliance on Wyeth's alleged misrepresentations.

Mrs. Scharff's arguments concerning the sufficiency of her fraudulent concealment allegations are misplaced at the summary judgment stage. Mrs. Scharff repeatedly argues that she has adequately pleaded "facts that warrant the tolling of the statute of limitations." (Doc. # 88, at 29; *see also* Doc. # 88, at 29-31 ("Scharff has pled the time and circumstances of her discovery of the cause of action. . . . Scharff has pled the facts and circumstances of Defendants' actions to conceal the cause of action. . . . Scharff has pled . . . that Defendants' concealment of facts prevented her from discovering the fact that her use of Prempro caused her cancer.")) However, "[i]n opposing a motion for summary judgment, a party may not rely on [her]

pleadings to avoid judgment against [her].” *Resolution Trust Corp. v. Dunmar Corp.*, 43 F.3d 587, 599 (11th Cir. 1995).

Looking beyond her pleadings, Mrs. Scharff has failed to produce evidence that Wyeth fraudulently concealed the existence of her cause of action. Mrs. Scharff’s evidence of Wyeth’s alleged fraudulent concealment consists of three internal letters sent by Wyeth sales representatives expressing their concerns about off-label promotion of Prempro and the side effects of the drugs,¹¹ and Wyeth’s alteration of the Prempro label after publication of the WHI study in 2002. (Doc. # 88, 30-31.) Mrs. Scharff argues that the changed Prempro label and these letters “demonstrate a pattern of conduct to conceal the risks associated with Defendants’ hormone therapy drugs, including Prempro, which is consistent with other evidence of Defendants’ course of concealment, including the language of the warning labels.” (Doc. # 88, at 30.) However, Mrs. Scharff has failed to explain the relevance of this evidence to

¹¹ The referenced internal letters sent by Charles Payne, Cynthia Waldrep, and Carl Whatley, Jr., Alabama sales representatives for Wyeth, to Wyeth management during the summer of 2000 expressing their concerns and misgivings about Wyeth’s promotion of hormone replacement therapy. (Doc. # 88, at 30; Doc. # 88, Exs. GG-II.) All three of these letters complain of Wyeth’s practice of promoting its hormone replacement drugs for off-label uses, and also make various references to the risk of breast cancer as a side effect. (Doc. # 88, Ex. GG (“many recent studies have shown increased incidences of breast cancer”); Ex. HH (“the issue of potential side effects has been minimized such as the risk of breast cancer”); Ex. II (“One of my biggest concerns however, is that such off-label promotion could conceivably lead to Premarin be [sic] prescribed in good faith by a physician who was influenced by the Alzheimer’s Disease Data and in a worse case scenario, the patient develops breast cancer, a thrombosis, or any other medical problem.”).)

show that Wyeth fraudulently prevented her from discovering or pursuing her causes of action arising from her development of breast cancer. *See, e.g., Abrams v. Ciba Spec. Chems. Corp.*, 666 F. Supp. 2d 1267, 1276 n.12 (S.D. Ala. 2009) (“To establish tolling on [the basis of fraud and concealment], plaintiffs must come forward with something more than vague statements of what was misrepresented or concealed, and must show specifically how it prevented them from filing suit earlier.”) (citing *Ball v. Union Carbide Corp.*, 385 F.3d 713, 724 (6th Cir. 2004)). Rather, as confirmed by the *Cazalas*, 435 So. 2d 55, and *Sellers*, 715 F.2d 1559, decisions discussed below, Mrs. Scharff’s evidence points not to fraudulent concealment of her cause of action by Wyeth, but instead to whether Wyeth fraudulently induced her to take Prempro or failed to adequately warn her of its dangers.

In *Sellers*, the plaintiff brought suit against a medical device manufacturer alleging negligence, wantonness, misrepresentation, fraud, and warranty claims for her injuries allegedly caused by use of the defendant’s intrauterine device. 715 F.2d at 1560. The plaintiff received the device in 1972, and in 1973 suffered a series of severe gynecological injuries. In 1980, she read a newspaper article about the intrauterine device and the alleged injuries it had caused, and subsequently filed suit in 1981. *Id.* In order to establish prima facie facts of fraudulent concealment, the plaintiff produced advertisements and internal memoranda from the defendant

manufacturer suggesting misrepresentations. *Id.* at 1561. The Eleventh Circuit found these materials relevant to the question whether the defendant fraudulently induced her use of the device, but irrelevant to “the issue of whether [the defendant] purposely prevented her from pursuing her claims.” *Id.* The court cited and analyzed persuasive and binding authority that the defendant manufacturer had no duty to disclose the plaintiff’s causes of action to her so that she could bring suit in a timely manner. *Id.* at 1562 (quoting *Sidney-Vinsein v. A.H. Robins Co.*, 697 F.2d 880, 884 (9th Cir. 1983) (“Once a plaintiff knows that harm has been done to him[,] he must . . . determine within the period of limitations whether to sue or not [F]ailure of the [defendant] to ascertain and publish the fact of its negligence is hardly sufficient to constitute fraudulent concealment.”); and *Tonsmeire v. Tonsmeire*, 233 So. 2d 465, 468 (Ala. 1970) (“In the absence of a confidential relationship, we know of no duty imposed by law obligating an alleged tortfeasor to make known to one possibly injured by his acts the existence of a possible cause of action.”)). Thus, the court found that the plaintiff had raised no genuine issue of material fact that the defendant medical device manufacturer had actively and fraudulently concealed her cause of action; therefore, her claims were untimely.

In *Cazalas*, the Alabama Supreme Court held that a manufacturer’s failure to warn of the risks of a product despite its knowledge of the product’s inherent danger,

without more, does not rise to the level of fraudulent concealment. 435 So. 2d at 58. The *Cazalas* plaintiffs, a group of shipyard workers, averred that the manufacturers of asbestos products fraudulently concealed their AEMLD, negligence, and wantonness causes of action because: (1) those defendants had known since the 1930s of evidence indicating the toxic properties of asbestos, (2) they refused to place warnings on packages containing asbestos-laden products, (3) when they did place warnings on their products, these warnings “failed to impart knowledge of the extent of the danger,” and (4) “the defendants failed to disseminate the information in such a way so as to apprise the plaintiffs of the danger.” *Id.* The plaintiff also contended that the asbestos manufacturers should have told local unions and employers of the risks of asbestos, and published notice of the risks of asbestos. The Alabama Supreme Court held that such allegations, taken as true, were insufficient to allege fraudulent concealment under Alabama law and instead merely alleged an actionable failure or refusal to warn by the defendants:

The allegations of the complaint allege a failure to warn on the part of the defendants. Under Alabama law, if a manufacturer or seller places goods on the market which are imminently dangerous when put to their intended purpose and the defendant knows or should know that the goods are dangerous when used in their customary manner, the defendant must exercise reasonable diligence to make such dangers known to the public likely to be injured by the product.

Id. (internal citations omitted).

Mrs. Scharff's evidence and arguments are similar to those of the plaintiffs in *Cazalas* and *Sellers*. She claims that Wyeth knew of the risk of breast cancer associated with Prempro in 1997 to 1999, that it published Prempro labels from 1997 to 1999 that failed to adequately warn of the danger of breast cancer, that the Prempro labels for 1997 to 1999 contained misrepresentations of that risk, and that the 2000 internal memoranda represent further evidence of those misrepresentations. (*See* Doc. # 88, at 29-31.) Like the evidence in *Sellers* and the averments in *Cazalas*, this evidence is not probative of any alleged misrepresentation that prevented Mrs. Scharff from making inquiry into the cause of her breast cancer or pursuing any claims arising from it. It may be relevant evidence of fraud involved in inducing her to take Prempro or a failure to warn, but that is insufficient to toll the statute of limitations. In addition, Mrs. Scharff has not produced any evidence that Wyeth owed her or her doctor a legal duty to inform them of her causes of action, or that Wyeth was in sole control and custody of the information surrounding her injury and cause of action. *See, e.g., DGB, LLC*, 55 So. 3d at 228 (finding sufficient allegations of fraudulent concealment where the plaintiffs alleged that defendants were in a fiduciary relationship with them and were entirely in control of the information concerning their cause of action and concealed it); *but see Tonsmeire*, 233 So. 2d at 468.

Moreover, there is no evidence that Mrs. Scharff's legal inaction from January 1999 through July 2002, and beyond, was induced by any representation by Wyeth, whether fraudulent or not. For a misrepresentation to constitute fraudulent concealment, it must have "induced Plaintiff to act or refrain from acting." *Soniat*, 626 So. 2d at 1258-59. Mrs. Scharff has not produced evidence of reliance by her doctor or her on misrepresentations made by Wyeth in deciding not to bring suit during this period.¹² Rather, she testified that though she might have glanced at the Prempro Patient Information Insert, she did not read it. Thus, by her own admission, the insert could not have played any role in her decision not to pursue her causes of action.

Further, even if there was evidence of fraudulent concealment, Mrs. Scharff's own testimony is that she did not ask her doctors about a link between her

¹² Mrs. Scharff has not argued that the learned intermediary doctrine applies to the fraudulent concealment inquiry, nor has the court undertaken that analysis. *See Sellers*, 715 F.2d at 1561-62 (relying on the plaintiff's failure to ask her doctor about the cause of her grave ailments) (decided after *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1275-76 (5th Cir. 1974) (discussing the learned intermediary doctrine's application in the medical prescription context)). Nevertheless, even applying the learned intermediary doctrine, Mrs. Scharff has not produced evidence of a misrepresentation made by Wyeth to Dr. Reiland that prevented him or Mrs. Scharff from discovering her cause of action. Dr. Reiland's testimony that the 2007 PDR was stronger and that he wished that information had been available in 1997-1999 is probative of a failure to warn, but not of fraudulent concealment sufficient for tolling. *Cazales*, 435 So. 2d at 58. Further, any reliance by Dr. Reiland on a misrepresentation by Wyeth is belied by his testimony that he was skeptical of the 1997/1998 PDR language, that there was conflicting literature about the breast cancer risk from hormone replacement therapy at that time, and that he was aware of the increased risk of breast cancer associated with hormone replacement therapy prior to the publication of the WHI study. (Dr. Reiland Dep. 39-40, 71.)

consumption of Prempro and her development of breast cancer. In fact, there is no evidence that she inquired about the cause of her breast cancer at all during this period. *See Sellers*, 715 F.2d at 1562 (“At no point, however, did [the plaintiff] ask her doctors what caused her medical problems.”). Mrs. Scharff’s evidence is that she took Prempro for about thirteen months, that she discovered a lump in her breast, that the lump was later determined to be cancerous, and that upon diagnosis, her doctor immediately instructed her to stop taking Prempro. Given these circumstances, “[a] person exercising due diligence would have been prompted to inquire about the cause of such grave ailments.” *Sellers*, 715 F.2d at 1562. Like the plaintiff in *Sellers*, this she did not do. Nor did she inquire generally into the causes of breast cancer, inquiries that could have revealed the contemporaneous studies that she now claims as evidence that Wyeth’s Prempro label constituted a fraudulent concealment of the risk of breast cancer from 1997 to 1999. *See infra*.

Finally, Mrs. Scharff also attempts to produce evidence of Wyeth’s fraudulent concealment of her cause of action from her by incorporating by reference a brief filed by another plaintiff in the case of *ChouEIFati v. Wyeth Pharms., Inc.*, No. 2003-49357A (Dist. Ct. Harris Cnty., Tex. Mar. 29, 2011). (Doc. # 88, at 29-30 & n.29 (“Scharff adopts and incorporates the factual statements and supporting exhibits demonstrating Defendants’ actions and attaches the relevant sections of the brief and

supporting exhibits as Exhibit FF.”.) The court has multiple concerns with Mrs. Scharff’s one-line incorporation-by-reference as it relates to her burden of establishing prima facie evidence of fraudulent concealment by Wyeth under Alabama law. None of these concerns are favorable for her cause.

First, a brief review of the Texas brief shows that it suffers from the same fatal flaw as her actual brief: it lacks evidence of misrepresentations made by Wyeth that prevented Mrs. Scharff from discovering her causes of action. The Texas brief relies on evidence that “Wyeth knew the majority of studies conducted by the date of the [Prempro] labels showed an increased risk of breast cancer,” thus arguing that Wyeth’s pre-WHI Prempro label constituted a misrepresentation. While the Texas brief and related evidence may be relevant to a fraud or failure to warn cause of action under Alabama law, Mrs. Scharff has not shown how they are relevant to how Wyeth prevented her from discovering or pursuing her causes of action.

Second, Mrs. Scharff’s one-line mention of the Texas brief does not include any argument of how Alabama tolling law or the circumstances of Mrs. Scharff’s case apply to these facts. *See, e.g., Resolution Trust Corp.*, 43 F.3d at 599 (“There is no burden upon the district court to distill every potential argument that could be made based upon the materials before it on summary judgment. Rather, the onus is upon the parties to formulate arguments”). Mrs. Scharff asks this court to assume her

burden of locating and citing relevant evidence of fraudulent concealment under Alabama law, and to comb through 937 pages of briefing and exhibits to pull out the facts necessary to bear her tolling burden.¹³ The implied request is declined. *See, e.g., Tolen v. Ashcroft*, 377 F.3d 879, 883 (8th Cir. 2004) (Where the plaintiff “failed to cite to specific portions of the record” in opposing summary judgment, “[t]he district court was not required to wade through his voluminous ‘Exhibit 1’ to find the existence of triable issues[.]”); *Jaurequi v. Carter Mfg. Co., Inc.*, 173 F.3d 1076, 1085 (8th Cir. 1999) (“[A] district court is not obligated to wade through and search the entire record for some specific facts which might support the nonmoving party’s claim.”) (internal citation and quotation marks omitted). The Texas brief does not aid Mrs. Scharff’s cause.

Because Mrs. Scharff’s claims accrued no later than January 18, 1999, and she did not bring her negligence and AEMLD claims against Wyeth on or before January 18, 2001, these claims are barred by the two-year statute of limitations. Therefore, the court need not consider the question of whether further tolling is warranted under *American Pipe & Construction Corporation v. Utah*, 414 U.S. 538 (1974).

¹³ The incorporation by reference of the Texas brief also violates the court’s General Briefing Order. (Doc. # 31, ¶ 7 (“Any discussion of evidence in a brief must include the *specific reference*, by name or document number and *by page and line*, to where *the evidence* can be found in the supporting evidentiary submission or in any document filed with the court.” (emphasis added).)

v. *Wantonness Claims*

As noted by Mrs. Scharff in her response to Wyeth's motion for summary judgment, Wyeth moved for summary judgment on every named count in Mrs. Scharff's Amended Complaint, but it did not address wantonness claims. (Doc. # 88, at 23-24.) Because Wyeth did not address her supposed wantonness claims on summary judgment, Mrs. Scharff argues that "[i]t is undisputed that Scharff's amended complaint contains causes of action that constitute claims of wantonness under Alabama law." (Doc. # 88, at 24.) Mrs. Scharff argues that her Amended Complaint included wantonness claims because she alleged in the final paragraphs of Counts I-III that Wyeth's "actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of [Mrs. Scharff] and the public. As such, plaintiff is entitled to punitive damages against [Wyeth]." (Doc. # 88, at 24; Am. Compl. ¶¶ 81, 90, and 97.) Mrs. Scharff also included a "Count VIII: Gross Negligence" and "Count IX: Claim for Exemplary Damages / Punitive Damages" alleging that Mrs. Scharff is due punitive damages because Wyeth acted fraudulently and with specific intent to cause her substantial injury. (Am. Compl. ¶¶ 125, 128.) Wyeth replies that Mrs. Scharff's Amended Complaint is a shotgun pleading that does not allege, much less mention, wantonness

claims, and that Mrs. Scharff may not further amend her complaint through argument in opposition to summary judgment. (Doc. # 131, at 17-20.)

Needless to say, the issue of whether Mrs. Scharff's Amended Complaint properly pled a wantonness claim is hotly disputed. The source of this tempest is an Alabama complaint that is substantively identical to the one filed in Minnesota state court in 2005. (*Concetta Alsin v. Wyeth*, Case No. 0:05-CV-227-JRT-JGL (D. Minn 2005) (Doc. # 1, Ex. 1).)

In Alabama, the term "wantonness" is statutorily defined as "[c]onduct which is carried on with a reckless or conscious disregard of the rights or safety of others." Ala. Code § 6-11-20(b)(3). The contours of the cause of action arising out of wanton conduct, however, are delineated by common law. The Alabama Supreme Court defined the cause of action for wantonness as:

the conscious doing of some act or the omission of some duty, while knowing of the existing conditions and being conscious that, from doing or omitting to do an act, injury will likely or probably result. To prove wantonness, it is not essential to prove that the defendant entertained a specific design or intent to injure the plaintiff.

Ex parte Capstone, 2011 WL 2164027, at *6 (citing *Ala. Mut. Ins. Co. v. Roush*, 723 So. 2d 1250, 1256 (Ala. 1998) (internal citations omitted)).

With the battle lines clearly drawn between Mrs. Scharff and Wyeth, the court finds that the substance of the averments in the Amended Complaint states a

wantonness cause of action under Alabama law. Though Mrs. Scharff did not label separate causes of action for wantonness, Counts I-III each allege that Wyeth's actions were not just negligent, but also conducted willfully, intentionally, and/or with reckless disregard for the rights of Mrs. Scharff and the public.¹⁴ (Am. Compl. ¶¶ 81, 90, 97.) Mrs. Scharff also alleges that Wyeth intentionally committed the acts alleged in Counts I-III with actual and subjective knowledge of the risk of harm to others and to the safety of the public. (Am. Compl. ¶¶ 125, 128.) Substance, not labels, governs.

Further, Wyeth's argument that the Amended Complaint does not include a claim for wantonness is undermined by its own Answer to the Amended Complaint stating that its conduct was not wanton or otherwise in accord with the intent or culpability averments used by Mrs. Scharff in paragraphs 81, 90, 97, 125, and 128 of her Amended Complaint. (Ans. 23 ("No act or omission of Wyeth was malicious, willful, wanton, reckless, grossly negligent or intentional and, therefore, any award of punitive damages is barred).) Rather than moving to dismiss these allegations in the Amended Complaint for failure to state a claim or moving to strike them as a shotgun pleading, Wyeth instead joined issue and answered with a defense. Stated another way, what is sauce for the goose (shotgun pleading) is sauce for the gander

¹⁴ Part V.A.vii addresses whether Mrs. Scharff's "wantonness under AEMLD" claims are timely.

(shotgun defense). *Cf. Teamsters & Emp'rs Welfare Trust of Ill. v. Gorman Bros. Ready Mix*, 283 F.3d 877, 882 (7th Cir. 2002) (Posner, J.). Wyeth's Answer confirms that it was on notice of Mrs. Scharff's wantonness claims and cannot (indeed, does not) now say it was prejudiced. Accordingly, Mrs. Scharff states a wantonness claim in her Amended Complaint.¹⁵

The analysis now turns to the appropriate statute of limitations for a wantonness claim under Alabama law.

vi. The Alabama Statute of Limitations for Wantonness

On June 3, 2011, during the pendency of Wyeth's motion for summary judgment, the Alabama Supreme Court issued *Ex parte Capstone*, overruling prior Alabama Supreme Court precedent and "conclud[ing] that claims alleging reckless and wanton conduct fall within the governance of the catchall provision in § 6-2-38(1) for a two-year limitations period" 2011 WL 2164027, at *7. In so ruling, the court overturned the holding of *McKenzie v. Killian*, 887 So. 2d 861, 870 (Ala. 2004), that "wanton conduct is the equivalent in law to intentional conduct [and that s]uch an allegation of intent renders the six-year statutory period of limitations applicable." *See Ex parte Capstone*, 2011 WL 2164027 at *3. In overruling *McKenzie*, the court

¹⁵ Because Mrs. Scharff's amended complaint contains wantonness claims and Wyeth did not move for summary judgment on the merits of the wantonness claims, Wyeth's motion for summary judgment is construed as a motion for partial summary judgment. (*See* Doc. # 77; Doc. # 131, at 17-20.)

noted, “*McKenzie* stands alone as an exception to the long line of cases that addressed the question of what statute of limitations was applicable to a claim of wantonness and that repeatedly answered that question by deciding that the two-year limitations period of § 6-2-38(1) was applicable.” *Id.* at *4 (citing nine Alabama Supreme Court cases decided between 1992 and 2002 holding that the applicable statute of limitations for a claim of wantonness is two years). “[U]ntil *McKenzie*, no decision of [the Alabama Supreme Court] ever applied the six-year statute of limitations of § 6-2-34(1) to a claim of wantonness, as that term is now understood.” *Id.* at *4.

Ex parte Capstone also included instructions regarding the retroactive application of the two-year statute of limitations for wantonness. The court noted that “retroactive application of judgments is the usual practice.” *Id.* at *11. However, the court expressed its concern about the constitutional aspect of shortening an existing statute of limitations, because “an existing cause of action is a vested right.” *Id.* Therefore, it stated that “this Court’s recognition today of a different statute of limitations than previously announced by this Court must ‘provide a reasonable time . . . for existing causes of action to be brought.’” *Id.* (quoting *Thomas v. Niemann*, 397 So. 2d 90, 93 (Ala. 1981)). Thus, the opinion carved out a class of plaintiffs to which the two-year statute of limitations would not retroactively apply. *Id.* at *12. The court described this class as those “who have been wantonly injured

within the last six years and who therefore have been entitled to rely upon the rule this Court announced in *McKenzie*.”¹⁶ *Id.*

In response to the *Ex parte Capstone* decision, this court directed the parties to brief that decision’s effect on the statute of limitations applicable to Mrs. Scharff’s wantonness claim. (Doc. # 194.) During the pendency of that briefing order, the Alabama Supreme Court issued yet another opinion concerning the wantonness statute of limitations, *Jerkins v. Lincoln Electric Company*, Case No. 1091533, 2011 WL 3573368 (Ala. June 30, 2011). Wyeth, and later Mrs. Scharff, brought *Jerkins* to the court’s attention. (Docs. # 205-206.) In *Jerkins*, the Alabama Supreme Court addressed a certified question from a Northern District of Ohio MDL court inquiring whether *McKenzie*’s wantonness six-year statute of limitations should be applied retroactively, prospectively, or in some other fashion. *Jerkins*, 2011 WL 3573368, at *2. The court responded to the question by noting that *Ex parte Capstone* overruled *McKenzie*, but that *Ex parte Capstone*’s ruling on the two-year statute of limitations for wantonness only applied prospectively. *Id.* at *8. The court thus adopted a simple test for determining the applicable wantonness statute of limitations under Alabama law: “Whether the wantonness claims of other individuals are subject to the two-year

¹⁶ As will be seen, this statement gets Mrs. Scharff into the timeliness bay, but not quite to shore. She *filed* within the six years immediately preceding *Ex parte Capstone*, but her cause of action *accrued* even before *McKenzie* was decided, by more than five years.

or six-year statute of limitations should therefore be determined based on whether those claims *were asserted* pre- or post-*Ex parte Capstone*.” *Id.* at *6 (emphasis added). Because Mrs. Scharff asserted her claims pre-*Ex parte Capstone*, this language gets Mrs. Scharff safely to the timeliness shore.

Despite *Jenkins*, Wyeth argues that a two-year statute of limitations applied at the time Mrs. Scharff’s claims accrued in 1999 and ran in 2001, and therefore *McKenzie* did not revive her then untimely wantonness claims. (Doc. # 205, at 2-4.) Wyeth also argues (1) that Mrs. Scharff is not entitled to rely on *McKenzie* after *Ex parte Capstone*, (2) that *Jenkins* is inconsistent with *Ex parte Capstone*, and (3) that *Ex parte Capstone* and *Jenkins* are unfair and wrongly decided under Alabama law and the Alabama Constitution. (Doc. # 205, at 5-9.) This court recognizes the inconsistency between the background rule of retroactivity of decisions discussed in *Ex parte Capstone*, 2011 WL 2164027, at *10-12; the subsequent carve-out language in *Ex parte Capstone* that the opinion would not apply retroactively “to cut off the claims of persons *who have been wantonly injured within the last six years* and who therefore have been entitled to rely upon the rule this Court announced in *McKenzie*[,]” *id.* at *12 (emphasis added); and *Jenkins*’s holding that *Ex parte Capstone* will *only* be applied prospectively. *Jenkins*, 2011 WL 2573368, at *6, 8. Despite this inconsistency, *Jenkins* clearly holds that wantonness claims *filed* before

Ex parte Capstone are subject to a six-year statute of limitations, and that holding is binding. See, e.g., *Technical Coating Applicators, Inc. v. U.S. Fid. and Guar. Co.*, 157 F.3d 843, 844 (11th Cir. 1998) (“[T]he federal court must follow the decisions of the state’s highest court when that court has addressed the relevant issue, [unless federal constitutional or statutory law compels a contrary result.]”). Thus, Mrs. Scharff’s common law wantonness claims, which were filed before the decision in *Ex parte Capstone*, are governed by a six-year statute of limitations under Alabama law.

Further, because the holding of *Jerkins* is unambiguous and raises no doubt about the interpretation of Alabama law, an *Erie* guess as to the statute of limitations applicable to Mrs. Scharff’s wantonness claims is unnecessary. See e.g., *Tobin v. Mich. Mut. Ins. Co.*, 398 F.3d 1267, 1274 (11th Cir. 2005). Therefore, Wyeth’s argument for certification to the Alabama Supreme Court is not persuasive. (Doc. # 205, at 9.) Accordingly, at this stage, Mrs. Scharff’s common law wantonness claim in Count I is timely under the applicable six-year statute of limitations. The last issue is whether the wantonness claims alleged in Counts II and III are likewise timely.

vii. AEMLD Claims, the Statute of Limitations, and Wantonness

Wyeth moved for summary judgment on the basis that Mrs. Scharff's AEMLD claims were barred by the two-year statute of limitations.¹⁷ (Doc. # 77, at 14.) Mrs. Scharff argues that her AEMLD claims in Counts II and III are not barred by the statute of limitations because "wantonness under AEMLD" is controlled by the six-year statute of limitations announced in *McKenzie and Carr v. International Refining and Manufacturing Company*, 13 So. 3d 947 (Ala. 2009). (Doc. # 88, at 26.) On the contrary, Mrs. Scharff's "wantonness under AEMLD" claims are barred by the statute of limitations.

To begin, Mrs. Scharff does not dispute that Counts II and III, entitled "Strict Products Liability," travel under AEMLD. (See Doc. # 88, at 35-41.) However, Mrs. Scharff has not cited binding Alabama case law supporting the proposition that a six-year statute of limitations applies to a claim of "wantonness under AEMLD," and there is none. Alabama's statute of limitations for an AEMLD claim is two years. Ala. Code § 6-2-38(1); *Malsch v. Bell Helicopter Textron, Inc.*, 916 So. 2d 600, 601 (Ala. 2005) (the plaintiffs' Alabama negligence, wantonness, and liability under AEMLD claims were subject to an "unambiguous two-year statute[] of limitations")

¹⁷ Further, the parties had notice and an opportunity to be heard regarding the timeliness of Mrs. Scharff's AEMLD claims sounding in wantonness. (See Docs. # 194, 204, 205.)

(decided after *McKenzie* and relied on in *Ex Parte Capstone*, 2011 WL 2164027, at *4); *Locke*, 899 So. 2d at 251 n.2 (Ala. Oct. 8, 2004) (decided after *McKenzie*); *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101, 103, 112 (Ala. 2003) (stating that the statute of limitations for the plaintiff’s claims of negligence, wantonness, and liability under AEMLD was two years); *see also Medtronic*, 607 So. 2d at 159 (An action alleging “liability under the AEMLD must be brought within two years after the cause of action accrued.”).

Mrs. Scharff’s reliance on *Carr* is misplaced on two grounds. First, *Ex parte Capstone* explained that *Carr*, as a plurality decision, is not binding precedent, and therefore did not merit analysis alongside *McKenzie*. 2011 WL 2164027 at *3. Therefore, *Carr* did not overturn Alabama’s settled two-year statute of limitations applicable to all claims of liability under AEMLD. That holding alone is sufficient to dispense with Mrs. Scharff’s reliance on *Carr*. However, the court also notes that *Carr* did not purport to create a new statute of limitations for AEMLD claims. In *Carr*, the plaintiffs filed a first amended complaint alleging negligence, wantonness, and liability under AEMLD, among other causes of action. *Carr*, 13 So. 3d at 950. After the case was remanded by an earlier opinion of the Alabama Supreme Court, the plaintiffs filed a second amended complaint alleging wantonness claims, but not AEMLD claims. *Id.* at 951. A cursory review of the plaintiffs’ wantonness pleadings

reveal that they track the elements of a common-law wantonness claim, not an AEMLD claim. *Id.* It was on that platform that the *Carr* plurality found that *McKenzie* created a six-year statute of limitations for a common law wantonness product liability claim. *Id.* at 955. Accordingly, the *Carr* plurality opinion did not disturb Alabama's settled two-year AEMLD statute of limitations. Therefore, summary judgment is due to be granted on Counts II and III in their entirety.

B. Causation

Wyeth's motion for summary judgment on causation is predicated on the granting of either its specific causation *Daubert* motion (Doc. # 104) or its general causation *Daubert* motion (Doc. # 105), thus depriving Mrs. Scharff of necessary evidence tending to show that her consumption of Prempro caused her breast cancer. (Doc. # 77, at 8-12.) Because the court has not ruled on these or other *Daubert* motions, ruling is reserved on Wyeth's summary judgment motion on causation.

VI. CONCLUSION

Accordingly, it is ORDERED that Defendants' motion for partial summary judgment (Doc. # 76) is GRANTED as to Plaintiff's negligence claim in Count I, and Counts II-VII in their entirety, and ruling is RESERVED on Defendants' causation argument. Plaintiff's remaining claims proceed solely on the common law theories that (1) Defendants wantonly breached a duty to adequately warn about Prempro's

risk of breast cancer and (2) Defendants wantonly designed Prempro. (*See Parties' Joint Proposed Order on Pretrial Hearing*, at 4-5, received June 20, 2011.) No other claims in the Amended Complaint remain.

VII. ORDER

Further, pursuant to Rule 56(f) of the Federal Rules of Civil Procedure, and in the interests of judicial economy and the parties' resources, it is ORDERED that Mrs. Scharff SHOW CAUSE, **on or before August 12, 2011**, why summary judgment should not be granted on her remaining wanton failure to warn and wanton design claims. *See, e.g., Toole v. McClintock (Toole I)*, 999 F.2d 1430 (11th Cir. 1993); *Richards v. Michelin Tire Corp.*, 21 F.3d 1048 (11th Cir. 1994); *Toole v. Baxter Healthcare Corp. (Toole II)*, 235 F.3d 1307 (11th Cir. 2000).¹⁸ Mrs. Scharff shall file a brief with argument and specific citation to relevant evidence sufficient to create a genuine issue of material fact on the remaining wantonness claims. Wyeth shall respond **on or before August 19, 2011**. The court will not entertain arguments about this Memorandum Opinion and Order or any other argument beyond Mrs. Scharff's remaining common law wanton failure to warn and wanton design claims.

¹⁸ This list of cases is provided for Mrs. Scharff's benefit and does not constrain the legal arguments the parties may make within the scope of the show cause order.

DONE this 2nd day of August, 2011.

/s/ W. Keith Watkins
CHIEF UNITED STATES DISTRICT JUDGE