IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

JUDITH HUGHES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION 08-0655-WS-N**
	)	
STRYKER SALES CORPORATION, *et al.*,	)	
	)	
Defendants.	)	

ORDER

This matter comes before the Court on the Motion for Summary Judgment (doc. 74) filed by defendants, Stryker Sales Corporation and Howmedica Osteonics Corp.[1] Also pending is defendants' Motion to Strike (doc. 86). The Motions have been briefed and are ripe for disposition.

I. Nature of Case.

Plaintiff, Judith Hughes, brought this products liability action against defendants, Stryker Sales Corporation ("Stryker Sales") and Howmedica Osteonics Corp. ("Howmedica"). Federal jurisdiction was predicated on diversity of citizenship, pursuant to 28 U.S.C. § 1332.[2] As alleged in the Complaint, Hughes underwent a right hip replacement in September 2007, wherein a prosthetic device called a "Trident Hemispherical Acetabular Shell" was implanted in her body.

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[1] Plaintiff's Complaint originally named a third defendant, Stryker Corporation. On February 10, 2009, the undersigned entered an Order (doc. 16) granting plaintiff's request for voluntary dismissal without prejudice of her claims against Stryker Corporation pursuant to Rule 41(a)(1), Fed.R.Civ.P. This Motion for Summary Judgment relates to all remaining claims as to all remaining defendants.

[2] The Complaint alleges that Hughes is an Alabama citizen, that Stryker Sales is a Michigan corporation whose principal place of business is located in Michigan, that Howmedica is a New Jersey corporation with its principal place of business in New Jersey, and that the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

The Complaint states that this device was designed, manufactured and marketed by Stryker Sales and Howmedica. Hughes' hip prosthesis later failed, as a result of which she underwent a revision surgery in July 2008 because of continued pain. Based on these factual allegations, Hughes brought state-law causes of action against defendants for products liability, negligence/wantonness, causation, and damages.[3]

In her products liability claim, Hughes asserts that the hip prosthesis was defective on the grounds that it "contained unsafe manufacturing residuals and/or bacteria," that it "was not sterile," that it "has a high propensity for delamination of the plasma sprayed coating to occur," that it "has a high propensity of poor bone fixation to occur," that it "has a high propensity for wear and fracture of the prosthesis to occur," that it "was marketed in such a way as to mislead consumers regarding its safety and efficacy," that it "was manufactured without adequate quality controls," and that it "was inadequately tested." (Doc. 1, ¶ 18.) Plaintiff contends that these defects rendered the device "unreasonable [*sic*] dangerous and defective." (*Id.*. ¶ 19.) Hughes' negligence/wantonness claims proceed along similar lines, with allegations that defendants were negligent and wanton in manufacturing, designing, marketing, and/or placing into the stream of commerce a hip prosthesis with the aforementioned defects. (*Id.*, ¶ 24.) Plaintiff seeks compensatory and punitive damages based on, among other things, her position that she "has suffered, and in reasonable probability, will continue to suffer serious and permanent injuries which will affect her for the rest of her life." (Doc. 1, ¶ 31.)

II. Summary Judgment Standard.

Summary judgment should be granted only if "there is no genuine issue as to any material fact and ... the movant is entitled to judgment as a matter of law." Rule 56(c), Fed.R.Civ.P. The party seeking summary judgment bears "the initial burden to show the district court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial." *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991). Once the moving party has satisfied its responsibility, the burden shifts to the nonmovant to

[3] Of course, there are no separate Alabama causes of action labeled "causation" or "damages"; rather, those items are elements of Hughes' other tort claims and not freestanding, distinct causes of action.

show the existence of a genuine issue of material fact. *Id.* "If the nonmoving party fails to make 'a sufficient showing on an essential element of her case with respect to which she has the burden of proof,' the moving party is entitled to summary judgment." *Id.* (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986)) (footnote omitted). "In reviewing whether the nonmoving party has met its burden, the court must stop short of weighing the evidence and making credibility determinations of the truth of the matter. Instead, the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Tipton v. Bergrohr GMBH-Siegen*, 965 F.2d 994, 999 (11th Cir. 1992) (internal citations and quotations omitted). "Summary judgment is justified only for those cases devoid of any need for factual determinations." *Offshore Aviation v. Transcon Lines, Inc.*, 831 F.2d 1013, 1016 (11th Cir. 1987) (citation omitted).

III. Analysis.

On its face, defendants' Rule 56 Motion turns on a singular, discrete issue. In particular, defendants seek summary judgment on all claims "based on the plaintiff's failure to present expert testimony supporting her claim that the prosthesis was defective and that it caused her injuries." (Doc. 76, at 3.) The only facts on which defendants rely consist of the claims joined in the Complaint; the Scheduling Order's requirement that plaintiff make expert disclosures pursuant to Rule 26(a)(2), Fed.R.Civ.P., on or before November 30, 2009; and plaintiff's failure to make expert disclosures at any time. Simply stated, defendants' Motion is predicated on the notion that plaintiff's failure to come forward with any expert testimony that the prosthetic hip was defective and that the defect caused her injuries is fatal to her ability to prevail on such claims at trial, such that entry of summary judgment for defendants is warranted.

A. The Expert Testimony Requirement.

As a threshold matter, defendants are correct that Hughes' state-law products liability cause of action implicates the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"). *See, e.g., Hogue v. Logan's Roadhouse, Inc.*, --- So.3d ----, 2010 WL 1265194, *3 (Ala.Civ.App. Apr. 2, 2010) ("The AEMLD is Alabama's version of products-liability law."). "Proof of an accident and injury alone is insufficient to establish fault under the AEMLD." *Verchot v. General Motors Corp.*, 812 So.2d 296, 303 (Ala. 2001) (citation omitted); *see also Kirk v. Garrett Ford Tractor, Inc.*, 650 So.2d 865, 867 (Ala. 1994) ("Mere proof that an accident

and injuries occurred is not enough to establish a prima facie case under the AEMLD."); *Townsend v. General Motors Corp.*, 642 So.2d 411, 415 (Ala. 1994) ("Proof of an accident and injury is not in itself sufficient to establish liability under the AEMLD; a defect in the product must be affirmatively shown."). Rather, "[t]he Plaintiff must prove that the product was substantially unaltered when used by him and must also prove causation in fact, including proof that the defect caused the injury and that the defect is traceable to the Defendant." *Sears, Roebuck & Co. v. Haven Hills Farm, Inc.*, 395 So.2d 991, 995 (Ala. 1981). In other words, a plaintiff bringing a products liability cause of action under Alabama law must establish, among other things, both that the product was defective and that the defect caused her injury. *See Goree v. Winnebago Industries, Inc.*, 958 F.2d 1537, 1541 (11th Cir. 1992) (in AEMLD setting, "[t]he plaintiff establishes a prima facie case as long as he provides sufficient evidence from which the jury could deduce that the product was defective, and that his injury was caused by the defect").

The pivotal question in this case is whether Hughes has made a sufficient showing of defectiveness and causation to reach a jury, even in the absence of expert testimony. It is well established in the AEMLD context that "ordinarily, expert testimony is required because of the complex and technical nature of the commodity." *Verchot*, 812 So.2d at 303 (citations omitted).[4]

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[4] In so finding, the undersigned heeds the Eleventh Circuit's admonition not to "overstate[] its case" by declaring "that expert testimony is always required to establish a defect under the AEMLD." *Goree*, 958 F.2d at 1541. The law is clear that expert testimony is not required under Alabama law "when a jury could reasonably infer from the product's failure under all the attendant circumstances that its defective condition caused the plaintiff's injury." *Id.* (citations and internal quotation marks omitted). This proposition is not only established under Alabama law, but is also consistent with precedents from other jurisdictions. *See, e.g., Krause Inc. v. Little*, 34 P.3d 566, 571 (Nev. 2001) ("expert testimony is not always necessary to establish the existence of a manufacturing defect"); *Wernimont v. International Harvestor Corp.*, 309 N.W.2d 137, 141 (Iowa App. 1981) ("Whether expert testimony is required [in a products liability case] ultimately depends on whether it is a fact issue upon which the jury needs assistance to reach an intelligent or correct decision."). For example, in *Interstate Engineering, Inc. v. Burnette*, 474 So.2d 624 (Ala. 1985), the plaintiff brought an AEMLD claim against the manufacturer of heat detectors that failed to sound an alarm when a fire broke out in plaintiff's home. The plaintiff's theory was that the heat sensors were defective. Based on the evidence presented at trial, the Alabama Supreme Court opined that "[w]hile the use of expert testimony would certainly have been preferable [to show that the heat detectors were defective], in light of the attendant circumstances of the case, it was not required." *Id.* at 628. Accordingly, the Court rejects defendants' overstated formulation that "[a]n essential element of all product liability

To establish a defective condition and causation, "expert testimony is *usually* essential and, therefore, usually required. If, however, under all the attendant circumstances, absent expert testimony, the jury could reasonably infer from the product's failure of performance that a defective condition caused the injury, a prima facie case has nonetheless been established." *Brooks v. Colonial Chevrolet-Buick, Inc.*, 579 So.2d 1328, 1332 (Ala. 19910 (citation omitted).[5] The critical question raised by the Motion for Summary Judgment in this case is whether, based on all attendant circumstances, Hughes has made a prima facie showing of defect and causation, despite her lack of supporting expert testimony.

B. Plaintiff's Non-Expert Evidence of Defect and Causation.

It is undisputed that Hughes made no expert disclosures and proffered no expert opinions that the prosthetic hip designed, manufactured and distributed by Stryker Sales and Howmedica was defective in the manner alleged in the Complaint, much less that any such defects caused Hughes "to suffer serious and permanent injuries which will affect her for the rest of her life" (doc. 1, ¶ 31), as she alleges. Hughes offers neither apologies nor excuses for that omission; rather, she maintains that this case falls into the category of AEMLD actions in which expert testimony is unnecessary. According to plaintiff, defendant Howmedica "has admitted to a manufacturing defect," and "information regarding performance of the hip implant is a matter within the common knowledge of jurors," such that expert testimony is not needed. (Doc. 82, at 5.)

Plaintiff submits four pieces of evidence that she contends are sufficient to raise a

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cases is expert testimony ... that a defect was the medical cause of plaintiff's claimed injuries." (Doc. 76, at 8.)

[5] *See also McClain v. Coca-Cola Co. Distributor*, 2009 WL 2985693, *6 (M.D. Ala. Sept. 16, 2009) ("Ordinarily, expert testimony is required in AEMLD cases to prove that the product is defective and that the defective condition of the product caused the product to fail and injure the plaintiff."); *McCreless v. Global Upholstery Co.*, 500 F. Supp.2d 1350, 1358 (N.D. Ala. 2007) ("There is no reason to find that this case merits an exception to the general rule that expert testimony is essential to the establishment of a defective condition in a product like a chair."); *Cook v. Sunbeam Products, Inc.*, 365 F. Supp.2d 1189, 1191-92 (N.D. Ala. 2005) (expert testimony is a necessary component of plaintiff's AEMLD case when product is of complex and technical nature, such that lay juror could not infer defect and causation without benefit of such testimony).

reasonable inference of a defect in her hip implant that caused her injury.[6] First, Hughes points to medical records showing that she received a total right hip replacement on September 14, 2007, at which time a prosthetic hip device manufactured by defendants was implanted in her body.[7] Second, she identifies a Thomas Hospital record reflecting that on or about July 1, 2008, her treating physician determined that Hughes "had suffered a hardware failure involving the acetabular cup with migration of the cup," such that she would need a second surgical procedure

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[6] Plaintiff has dumped more than 500 pages of exhibits into the summary judgment record, including some 485 pages of medical records. (*See* docs. 82-84.) Of those 485 pages, Hughes cites to a grand total of 5 of them in her summary judgment brief. (Doc. 82, at 3 n.3&4.) This tactic of bulk-filing superfluous, unexcerpted exhibits is improper for at least three reasons. First, plaintiff has contravened the express prescription in the Local Rules that "[i]f discovery materials are germane to any motion or response, only the relevant portions of the material shall be filed with the motion or response." Local Rule 5.5(c). Second, by not furnishing hard copies of these voluminous exhibits to the undersigned, plaintiff has violated the Magistrate Judge's directive that "[i]f a party's exhibits in support of or in opposition to a motion exceed 50 pages in the aggregate, then that party must deliver a courtesy hard copy of those exhibits to the Judge's chambers by mail or hand delivery." (Doc. 38, ¶ 13(c).) Third, to the extent that plaintiff would have the Court sift through her mountain of exhibits for items that might lend support to her arguments on summary judgment, she cannot shirk or shift her Rule 56 burden in that fashion. Simply put, this Court will not scour the uncited portions of Hughes' evidentiary submission for any scrap of evidence that may advance her position. *See, e.g., Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 672 (10th Cir. 1998) (federal courts "are wary of becoming advocates who comb the record of previously available evidence and make a party's case for it"); *Preis v. Lexington Ins. Co.*, 508 F. Supp.2d 1061, 1068 (S.D. Ala. 2007) ("Parties may not, by the simple expedient of dumping a mass of evidentiary material into the record, shift to the Court the burden of identifying evidence supporting their respective positions."); *Witbeck v. Embry Riddle Aeronautical University, Inc.*, 219 F.R.D. 540, 547 (M.D. Fla. 2004) ("That judges have no duty to scour the file in search of evidence is an obvious corollary to the requirement that parties specifically identify the portions of the case file which support their assertions regarding whether genuine issues remain for trial."). "Instead, review of the parties' submissions is restricted to the portions of the record they have cited ...." *Rowell v. Winn Dixie*, 2008 WL 4369003, *1 n.3 (S.D. Ala. Sept. 23, 2008) (citations omitted).

[7] This fact is undisputed and will be accepted on summary judgment; however, plaintiff's only record citation in support of this fact is to page 152 of Exhibit D, which is a sheet of difficult-to-decipher handwritten physician progress notes that address issues such as knee pain (with an apparent reference to torn cartilage) and constipation. That page also reflects that Hughes was experiencing "numerous other issues" relating to her health at that time. (Doc. 83, Exh. D, at 152.) Certainly nothing on that page indicates that "Plaintiff received a Trident acetabular cup" (doc. 82, at 3), which is the sole proposition for which Hughes cites it.

called a "[r]evision of right total hip arthroplasty." (Doc. 84, Exh. E, at 29.) Third, Hughes relies on a document labeled "Warning Letter," dated March 15, 2007, and sent from the U.S. Department of Health and Human Services to a company called Stryker Ireland, Ltd., Orthopaedics, in Cork, Ireland. (Doc. 82, Exh. A.) This Warning Letter states that an inspection of the manufacturing facility in the fall of 2006 had revealed several violations of regulations promulgated under the Federal Food, Drug, and Cosmetic Act.[8] Fourth, plaintiff relies on a Stryker document labeled "Urgent Product Recall" and dated January 24, 2008 (the "Recall Letter"), providing that all Trident Hemispherical and PSL Shells manufactured at the company's Cork, Ireland facility between January 2000 and December 2007 were being recalled on the ground that "additional testing that was conducted as a regular part of internal procedure determined that the average level of manufacturing residuals in some cases exceeded Stryker Orthopaedics' self imposed conservative acceptance criteria." (Doc. 82, Exh. B, at 2.) The Recall Letter explained that "[t]he potential hazard ... is that the device may not achieve biological fixation," but hastened to add that "failure to achieve biological fixation may result from many factors unrelated to the device." (*Id.*)

C. Adequacy of Plaintiff's Evidence on Summary Judgment.

Hughes interprets her own evidence as demonstrating that "the Defendant has admitted the existence of a manufacturing defect" and that defendants' argument on expert testimony is an "attempt[] to increase the costs and time required to prepare and try this case." (Doc. 82, at 6.) This contention cannot withstand scrutiny for several reasons. First, it is simply untrue that Stryker Sales and Howmedica have admitted that Hughes' prosthetic hip had a manufacturing

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[8] Those violations included the following: (a) "Failure to establish and maintain adequate procedures for implementing a corrective and preventative action," (b) "Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements," (c) "Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems," and (d) "Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications." (Doc. 82, Exh. A, at 2-7.) The Warning Letter indicates that the items manufactured at Stryker Ireland's County Cork facility include numerous types of sterile orthopedic implants, and does not specify any violations specific to the Trident Acetabular System at issue in this case, much less the particular unit received by plaintiff.

defect. The Recall Letter says only that internal testing revealed that, while industry acceptance criteria and sterilization standards were met, "the average level of manufacturing residuals ***in some cases*** exceeded Stryker Orthopaedics' ***self imposed conservative acceptance criteria***." (Doc. 82, Exh. B at 2 (emphasis added).) Defendants' concession that in some cases residuals exceeding conservative company-imposed limits (which were more stringent than industry standards) were found is hardly a *mea culpa* that all (or any) devices manufactured at that facility were defective or unreasonably dangerous, and cannot reasonably support such an inference. Moreover, that same Recall Letter set forth defendants' "determination that plaintiffs implanted with the affected product ***are not at an increased risk***." (*Id.* (emphasis added).) This language is a far cry from being an admission of a manufacturing defect, and does not support plaintiff's assertion that defendants have "admitted the existence of a manufacturing defect" (doc. 82, at 5).

Second, plaintiff makes no attempt to reconcile her position with Rule 407 of the Federal Rules of Evidence, which generally bars evidence of subsequent remedial measures "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction." Rule 407, Fed.R.Evid. The Recall Letter was dated four months after Hughes received her prosthetic hip, and plaintiff relies on it for the sole purpose of showing a product defect, not for any permitted purpose enumerated in Rule 407. Accordingly, the Recall Letter would appear to lie within the ambit of Rule 407's prohibition.[9]

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[9] There is considerable authority from other jurisdictions that product recalls such as that at issue here, and occurring after the injury or harm, are not admissible to prove a product defect. *See, e.g., Rutledge v. Harley-Davidson Motor Co.*, 2010 WL 445498, *3 (5th Cir. Feb. 3, 2010) (where motorcycle manufacturer issued recall notices after plaintiff's accident, and plaintiff sued manufacturer for products liability, "the district court correctly identified the recall notices as subsequent remedial measures under Rule 407" and "did not abuse its discretion in excluding the notices"); *Chase v. General Motors Corp.*, 856 F.2d 17, 21 (4th Cir. 1988) ("we are of opinion that evidence of the fact of recall was improperly admitted under Rule 407"); *Hughes v. Boston Scientific Corp.*, 669 F. Supp.2d 701, 715-16 (S.D. Miss. 2009) (in products liability case involving medical device, defendant's "recall notices were inadmissible to prove a defect" and "evidence of the voluntary [device] recall is irrelevant to the facts of the case and inadmissible under Rule 407"); *In re Propulsid Products Liability Litigation*, 2003 WL 1090235, *2 (E.D. La. Mar. 11, 2003) ("product recalls are subsequent remedial measures for purposes of Rule 407") (citation omitted); *Pesce v. General Motors Corp.*, 939 F. Supp. 160, 165 (N.D.N.Y. 1996) ("Before a recall letter can be admitted into evidence, the plaintiff must lay a proper foundation, independent of the recall itself, establishing that a defect existed"); *Buckman v.*

Third, plaintiff does not explain how the mere fact of a product recall gives rise to a reasonable inference that the actual device implanted in Hughes had a defect. As discussed previously, the Complaint includes allegations that Hughes' device was defective because it "contained unsafe manufacturing residuals and/or bacteria," "was not sterile," "has a high propensity for delamination of the plasma sprayed coating to occur," "has a high propensity of poor bone fixation to occur," "has a high propensity for wear and fracture of the prosthesis to occur," "was marketed in such a way was to mislead consumers regarding its safety and efficacy," "was manufactured without adequate quality controls," and "was inadequately tested." (Doc. 1, ¶ 18.) Hughes offers no indication of how the Recall Letter shows that the actual device she received in September 2007 suffered from any of these enumerated shortcomings. The Recall Letter expressly stated that past recipients of the implants (such as Hughes) were not at increased risk, and that the recall was prompted by a finding that the "average level" of residuals "in some cases" exceeded stringent internal criteria, even though industry standards were met. Based on that Recall Letter alone, it would be an unreasonable and unsupportable inferential leap for a finder of fact to conclude that Hughes' prosthesis "contained unsafe manufacturing residuals and/or bacteria," rendering it dangerously defective for AEMLD purposes.

In light of the evidentiary and logical problems with Hughes' reliance on the Recall Letter as proof of a defect, the Court looks to her other evidence to determine whether it might remedy these shortcomings. It does not. The medical records cited by plaintiff certainly support an inference that her hip prosthesis failed; indeed, a summary from July 2008 includes a physician's determination that Hughes "had suffered a hardware failure involving the acetabular cup." (Doc. 84, Exh. E, at 29.) But Alabama law is crystal clear that the mere failure of a product does not presuppose the existence of a defect; instead, a defect must be affirmatively shown. *See, e.g., Townsend*, 642 So.2d at 415 ("the failure of a product does not presuppose the existence of a defect" and AEMLD requires that "a defect in the product must be affirmatively shown"); *Brooks*, 579 So.2d at 1333 ("The doctrine of *res ipsa loquitur* is not applicable in

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Bombardier Corp., 893 F. Supp. 547, 554 (E.D.N.C. 1995) ("the engine stop switch recall letter functions as a subsequent remedial measure under Rule 407," and "Plaintiff is therefore barred from introducing evidence of the engine stop switch recall" to show a defect in the product).

products liability cases - mere proof of the accident itself is not proof of a defective product ....”). Thus, the mere fact that Hughes experienced a “hardware failure” (*i.e.*, the bare fact that her hip prosthesis failed) does not satisfy her burden of affirmatively showing that the product was defective. And the Warning Letter says nothing about the presence of residuals in any Trident acetabular cups, much less the specific cup in plaintiff’s implant; therefore, it cannot constitute an affirmative showing of a defect in plaintiff’s device, even assuming it otherwise to be admissible.

Setting aside the question of defect, Hughes’ efforts to establish a prima facie cause of action under the AEMLD also are lacking on the element of causation. As noted *supra*, Alabama law requires a plaintiff to “prove causation in fact, including proof that the defect caused the injury.” *Sears, Roebuck*, 395 So.2d at 995. There is no record evidence from which a factfinder could reasonably conclude that Hughes’ claimed injuries were caused by any defect in the product. Unquestionably, an implanted hip prosthesis is a complex and technical device, the operation and mechanics of which extend well beyond the ken of lay jurors. The record evidence in plaintiff’s own summary judgment submission is that the failure of such a device “to achieve biological fixation may result from many factors unrelated to the device.” (Doc. 82, Exh. B, at 2.) Plainly, there are other possible causes of Hughes’ injury, none of which she has attempted to refute. Moreover, plaintiff’s evidentiary submission reflects that Hughes herself had “numerous” medical issues at the time she received the prosthesis. (Doc. 83, Exh. D, at 152.) The interaction between a complex and technical medical device and the unique physiological and medical circumstances of the patient in which it is implanted is a subject on which no ordinary juror could rationally be expected to have knowledge. The net result is that, without the benefit of expert testimony, a reasonable jury could not possibly make a determination on this summary judgment record that Hughes’ injuries were caused by a manufacturing or design defect in the prosthetic hip. The mere failure of the device is not proof that it was defective for AEMLD purposes. And there may be innumerable possible reasons for the failure of the device and the need for a revision surgery that are wholly divorced from, and independent of, any defect (such as manufacturing residuals) that the device may have had.

All of these proof problems underscore the compelling reasons why expert testimony is often deemed essential to a plaintiff’s ability to meet the parameters of a prima facie case of

products liability under Alabama law. In the typical case involving a complex medical device, the absence of expert testimony would force a jury to engage in speculation and conjecture on issues of defect and causation, much as Hughes is proposing here.[10] Therefore, courts routinely require expert testimony in such matters. *See, e.g.*, *Bloodsworth v. Smith & Nephew, Inc.*, 476 F. Supp.2d 1348 (M.D. Ala. 2006) (in AEMLD action alleging defective acetabular cup in prosthetic hip implant, finding that "expert testimony is a necessary ingredient" of plaintiffs' case because prosthesis is "of a complex and technical nature" from which lay jurors could not infer defective condition without expert testimony); *Benedict v. Zimmer, Inc.*, 405 F. Supp.2d 1026, 1033-34 (N.D. Iowa 2005) (in prosthetic hip case, finding that expert evidence was required for plaintiffs to survive summary judgment because "[w]hether the device had a design defect, whether the foreseeable risks of harm the device could have been reduced or avoided ... and whether the omission of such design rendered the device not reasonably safe are technical, scientific issues that cannot be fully understood by the average juror without some expert assistance" and where causation was "a complex medical issue that is beyond common knowledge and experience" given plaintiff's history of medical problems); *Oiler v. Biomet Orthopedics, Inc.*, 2004 WL 325389, *8 (E.D. La. Feb. 17, 2004) ("A determination of whether Oiler's post-operative complications could have been caused by a contaminated prosthesis, in addition to whether the prosthesis was in fact contaminated, are issues that require expert testimony; such a determination requires specialized medical knowledge not within the average person's common understanding."); *see generally McClain v. Coca-Cola Co. Distributor*, 2009 WL 2985693, *6 (M.D. Ala. Sept. 16, 2009) (granting defendant's motion for summary judgment as to AEMLD claim alleging defective soft drink can, where design and manufacture of can are complex and technical matters, plaintiff failed to offer expert testimony, and deadline to disclose expert witnesses had long since expired).

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[10] For example, Hughes would have the jury speculate that the quality control problems outlined in the Warning Letter caused her hip prosthesis to be defective, that her prosthesis included elevated manufacturing residuals of the type identified in the Recall Letter, that those residuals rendered the product defective for purposes of the AEMLD, and that this defect in her prosthesis caused its failure. The record evidence is simply insufficient to permit a reasonable finder of fact to make any of these determinations without the benefit of expert testimony.

For all of these aforementioned reasons, the Court finds that this case falls squarely within the general rule. Expert testimony is integral to Hughes' ability to satisfy her prima facie burden of establishing a defect and causation. Stated differently, a lay jury could not sort out the fundamental proof issues in plaintiff's favor on this evidentiary showing without engaging in impermissible and improper conjecture as to matters extending well beyond their common knowledge and experience. As such, much as the plaintiffs in the *Bloodsworth*, *Benedict* and *Oiler* cases described *supra*, Hughes has failed to satisfy her threshold evidentiary burden to withstand defendants' Motion for Summary Judgment.

In her April 9, 2010 Response to the Motion for Summary Judgment, Hughes wrote that "if the Court believes expert testimony is necessary ..., in the interests of justice, Plaintiff does request leave to designate expert witnesses." (Doc. 82, at 6.) But the Rule 16(b) Scheduling Order entered in March 2009, provided that "[t]he disclosure of expert testimony, including reports, required by Fed.R.Civ.P. 26(a)(2) is to be made by Plaintiff on or before **November 30, 2009**." (Doc. 38, ¶ 6.) More than four months after that deadline, Hughes made a conclusory request to be allowed to designate experts. In effect, what Hughes asks is that long-expired deadlines in the Rule 16(b) Scheduling Order be excavated and reset to allow her to come forward with expert disclosures now. However, scheduling orders "may be modified only for good cause and with the judge's consent." Rule 16(b)(4), Fed.R.Civ.P. The Rule 16(b) "good cause" standard "precludes modification unless the schedule cannot be met despite the diligence of the party seeking the extension." *Sosa v. Airprint Systems, Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998).[11] Plaintiff has not even attempted to make a showing of diligence that might satisfy the Rule 16(b)(4) requirement for modifying the scheduling order. There is no indication, for example, that plaintiff simply overlooked the deadline, that despite diligence she was unable to locate an expert in a timely manner, or even that she has consulted with any expert at any time as

[11] *See also Romero v. Drummond Co.*, 552 F.3d 1303, 1319 (11th Cir. 2008) ("To establish good cause, the party seeking the extension must have been diligent."); *Abrams v. Ciba Specialty Chemicals Corp.*, 2009 WL 1658525, *2 (S.D. Ala. June 12, 2009) ("In assessing the presence or absence of good cause, the Court recognizes that carelessness is not compatible with a finding of diligence and offers no reason for a grant of relief.") (citations and internal quotation marks omitted).

to the facts of the case. By all appearances, Hughes took a calculated risk that expert testimony would not be needed to prove up her claims. That this gamble did not pay off cannot properly be equated to either good cause nor diligence. Accordingly, plaintiff's request to designate expert witnesses now, some five months after the Rule 16(b) deadline, one month after the close of discovery, and less than three months before trial is **denied**.[12]

D. The Negligence and Wantonness Claims.

The remaining question concerns the fate of Hughes' negligence and wantonness claims. There is no doubt that, under Alabama law, plaintiff's AEMLD cause of action is distinct from those sounding in negligence and wantonness.[13] Nonetheless, it is hornbook law that a plaintiff seeking to prevail on theories of negligence or wantonness must show, *inter alia*, breach of duty and causation. *See, e.g., QORE, Inc. v. Bradford Bldg. Co.*, 25 So.3d 1116, 1123 (Ala. 2009) ("In a negligence action the plaintiff must prove (1) that the defendant owed the plaintiff a duty; (2) that the defendant breached that duty; (3) that the plaintiff suffered a loss or injury; and (4)

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[12] The result would be unchanged if plaintiff's request were viewed through the prism of Rule 37(c)(1), which provides that if a party fails to disclose a witness in a timely manner, "the party is not allowed to use that ... witness to supply evidence on a motion ... unless the failure was substantially justified or is harmless." Rule 37(c)(1), Fed.R.Civ.P. Plaintiff has made no showing of substantial justification or harmlessness, nor could she do so. In light of the legal principles outlined above and the formidable proof problems she faced, Hughes could have recognized the necessity of expert testimony from the outset of this action; therefore, her failure timely to disclose an expert was not substantially justified. Further, her omission was not harmless because defendants prepared their summary judgment motion on the premise that Hughes would be offering no expert testimony. To allow Hughes to designate an expert now would be to negate defendants' summary judgment motion, to compromise the August 2010 trial setting, and to guarantee the need for re-opener of discovery, thereby ratcheting up the effort, expense and delay for all concerned based on an expert disclosure matter that plaintiff could and should have addressed some time ago.

[13] *See, e.g., Vesta Fire Ins. Corp. v. Milam & Co. Const., Inc.*, 901 So.2d 84, 102 (Ala. 2004) (rejecting premise that AEMLD subsumes common-law tort actions of negligence and wantonness); *Spain v. Brown & Williamson Tobacco Corp.*, 872 So.2d 101, 105-06 (Ala. 2003) (explaining that AEMLD does not abrogate the common law, and that negligence and wantonness claims may be viable alternatives to AEMLD claim); *Tillman v. R.J. Reynolds Tobacco Co.*, 871 So.2d 28, 35 (Ala. 2003) ("We will not presume to so define the boundaries of the judicially created AEMLD so that it subsumes the common-law tort actions of negligence and wantonness ....").

that the defendant's breach was the actual and proximate cause of the plaintiff's loss or injury.") (citations omitted); *Proctor v. Classic Automotive, Inc.*, 20 So.3d 1281, 1287 (Ala.Civ.App. 2009) (wantonness requires proof that defendant, with reckless indifference to consequences, consciously and intentionally did a wrongful act or omitted a known duty, and "that act or omission must proximately cause the injury of which the plaintiff complains") (citation omitted).

Hughes insists that she can show breach of duty because there is circumstantial evidence that defendants negligently manufactured the hip prosthesis. (Doc. 82, at 7.) However, her Response is silent on the question of causation. Of course, "[p]roximate cause is an essential element of both negligence claims and wantonness claims." *Gooden v. City of Talladega*, 966 So.2d 232, 239 (Ala. 2007) (citations omitted). Moreover, "the question of proximate cause may be decided by a summary judgment if there is a total lack of evidence from which the fact-finder may reasonably infer a direct causal relation between the culpable conduct and the resulting injury." *Id.* at 240 (citations and internal quotation marks omitted). From what evidence could the jury reasonably infer a direct causal relation between defendants' purportedly culpable conduct (*i.e.*, negligently manufacturing the device) and Hughes' injury? There is none. The record establishes that plaintiff's hips prosthesis failed, but there is nothing other than idle speculation as to why. No evidence links the failure of that complex, technical medical device to any negligent or wanton conduct by defendants; to the contrary, it could have failed for myriad reasons totally unrelated to any negligent acts or omissions by defendants. As such, plaintiff has failed to come forward with evidence that might give rise to a jury question as to whether defendants' purported negligence and wantonness proximately caused her injuries. *See generally Cordoba v. Dillard's, Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005) ("Speculation does not create a *genuine* issue of fact; instead it creates a false issue, the demolition of which is a primary goal of summary judgment.") (citation omitted); *Holifield v. Reno*, 115 F.3d 1555, 1564 n.6 (11th Cir. 1997) (plaintiff's conclusory assertions "in the absence of supporting evidence, are insufficient to withstand summary judgment"). Therefore, defendants are entitled to entry of summary judgment as to plaintiff's negligence and wantonness causes of action, as well. *See generally McCreless v. Global Upholstery Co.*, 500 F. Supp.2d 1350, 1358-59 (N.D. Ala. 2007) (based on determination that AEMLD claim failed for want of expert testimony on defect and causation, granting summary judgment on negligence and wantonness theories "[b]ecause

defective design or manufacture and proximate cause are essential elements of all theories being pursued ..., and because ... [plaintiff] has no evidence to support these essential elements").

IV. Conclusion.

For all of the foregoing reasons, defendants' Motion for Summary Judgment (doc. 74) is **granted** and this action is **dismissed with prejudice**. In light of these determinations, defendants' Motion to Strike (doc. 86) is **moot**.

A separate judgment will enter.

DONE and ORDERED this 13th day of May, 2010.

s/ WILLIAM H. STEELE
CHIEF UNITED STATES DISTRICT JUDGE