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

ODESSA MOSLEY, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**CIVIL ACTION NO. 09-0284-KD-C**
	)	
WYETH, INC., et al.,	)	
	)	
Defendants.	)	
	)	

ORDER

This matter is before the Court on Actavis, Inc. and Actavis-Elizabeth, LLC (collectively, "Actavis")'s motion for summary judgment (Doc. 81) and reply brief (Doc. 87) and the plaintiffs' response and memorandum in opposition (Doc. 85).

For the reasons set forth herein, Actavis' motion for summary judgment is **DENIED**.

I. Summary Judgment Standard

Summary judgment should be granted only if "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c).[1] 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."

[1] Rule 56(c) of the Federal Rules of Civil Procedure, provides that summary judgment shall be granted:

> if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

FED. R. CIV. P. 56 (c).

Clark v. Coats & Clark, Inc., 929 F.2d 604, 608 (11th Cir. 1991). The party seeking summary judgment also always bears the "initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Id. (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). 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. *Celotex*, 477 U.S. at 323. However, "[i]n 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, 998-999 (11th Cir. 1992), *cert. den.*, 507 U.S. 911 (1993) (internal citations and quotations omitted). The mere existence of a factual dispute will not automatically necessitate denial; rather, only factual disputes that are material preclude entry of summary judgment. *Lofton v. Secretary of Dep't of Children & Family Serv.*, 358 F.3d 804, 809 (11th Cir. 2004), *cert. den.*, 534 U.S. 1081 (2005).

II. Analysis

A. Background

Plaintiffs Odessa and Ulysses Mosley initiated this lawsuit by filing a complaint in this Court on May 21, 2009, alleging claims sounding in negligence, strict liability, breach of warranty, misrepresentation and fraud, and gross negligence. (Doc. 1). Jurisdiction obtains pursuant to 28 U.S.C. § 1332. (Docs. 1, 19, 27 & 103).

The plaintiffs claim that sometime in 2005, Odessa Mosley's treating physician prescribed Reglan at a dosage of 10 mg to treat her reflux, nausea and vomiting. (Doc. 1, ¶ 3.08) . The active ingredient in Reglan is metoclopramide and metoclopramide HC1, a dopamine antagonist. (*Id*. at ¶ 3.09). Mrs. Mosley alleges that after she ingested the Reglan as prescribed on a long-term basis, she began exhibiting abnormal body movements "which have since been linked to her use of Reglan/metoclopramide." (*Id*. at ¶¶ 3.11-3.13, & 3.15). Mrs. Mosley also claims that she developed a movement disorder called tardive dyskinesia as a result of taking Reglan/metoclopramide. (*Id*. at ¶¶ 3.16).

The plaintiffs allege that Actavis is a manufacturer, marketer and distributor of generic metoclopramide. (*See id*. at ¶¶ 3.05 & 3.59). Actavis was formerly known as "Purepac." (Doc. 81-1, p. 3; Doc. 103).

The Rule 16(b) scheduling order governing this case required the plaintiffs to provide affirmative product identification evidence and initial disclosures to the defendants on or before September 4, 2009. (Doc. 53). The plaintiffs timely served all counsel of record with a Notice of Product Identification and Initial Disclosures. (Doc. 81-2). To the Initial Disclosures, they attached 20 pages of pharmacy records from Target Pharmacy ("Target Records") and 42 pages of records from Walgreens Pharmacy ("Walgreens Records"), as well as "Billing Records Affidavits" from Tammy Irby, who is identified as the "custodian"/"person in charge of records of Walgreen's Pharmacy," and from Connie M. Childs, who is identified as the "custodian"/"person in charge of records of Target Pharmacy." (*See* Doc. 81-2, pp. 9-10; 81-3; & 81-4)

Irby's affidavit states that the Walgreens Records "provide an itemized statement of the service and the charge for the service that Walgreens Pharmacy provided to Odessa Mosley . . . for

treatment rendered from [] 2/18/2002 to [] 3/26/2009." (Doc. 81-3). Irby also attests that she keeps "[t]he attached [] 42 pages of documents . . . in the regular course of business," and that the "information contained in the records was transmitted to [Irby] in the regular course of business by Walgreens Pharmacy or an employee or representative of Walgreens Pharmacy who had personal knowledge of the information." *Id.* Finally, Irby states that the records "are . . . originals or exact duplicates of the original" records that were "made at or near the time or reasonably soon after the time that the service was provided." *Id.*

Likewise, Childs' affidavit states that the Target Records "provide an itemized statement of the service and the charge for the service that Target Pharmacy provided to Odessa Mosley . . . for treatment rendered from [] Jan[uary] 1, 2005 to [] March 13, 2009." (Doc. 81-4). Childs also attests that she keeps "[t]he attached [] 20 pages of documents . . . in the regular course of business," and that the "information contained in the records was transmitted to [Childs] in the regular course of business by Target Pharmacy or an employee or representative of Target Pharmacy who had personal knowledge of the information." *Id.* Finally, Childs states that the records "are . . . originals or exact duplicates of the original" records that were "made at or near the time or reasonably soon after the time that the service was provided." *Id.*

The Walgreens Records contain three sets of entries that mention both metoclopramide and Purepac:

Entry Set One

On the page of the Walgreens Records Bates-labeled "000010" (Doc. 81-3, p. 12), there is an entry row containing the following information:

- Under a column labeled "RX Number": "RX 0130424"

- Under a column labeled “Drug Name”: “Metoclopramide 10 MG Tablets”
- Under a column labeled “Drug Mfr”: “Purepac”
- Under a column labeled “Plan”: “ALBC”
- Under a column labeled “Claim #”: 1016944116180117601
- Under a column labeled “Doc Name”: “Lauten, S”
- Under a column labeled “Orig Date”: “09/28/2006”
- Under a column labeled “Qty”: “120”
- Under a column labeled “Refills”: “8”
- Under a column labeled “Days Supply”: “30”

Id.

Entry Set Two

On the page of the Walgreens Records that is Bates-labeled “000015" (Doc. 81-3, p. 17), there is an entry row containing the following information:

- Under a column labeled “RX Number”: “RX 0130428”
- Under a column labeled “Drug Name”: “Metoclopramide 10 MG Tablets”
- Under a column labeled “Drug Mfr”: “Purepac”
- Under a column labeled “Doc Name”: “Lauten, S”
- Under a column labeled “Orig Date”: “09/28/2006”
- Under a column labeled “Qty”: “120”
- Under a column labeled “Refills”: “8”
- Under a column labeled “Days Supply”: “30”

Id.

Underneath those entries, a subset of eight entries appear under columns labeled as follows:

"Enter Date"	**"ENT/ VER"**	**"Fill Qty"**	**"Refill"**	**"Cust Amt"**	**"Tot Amt"**	**"Fill Sold Date"**	**"Plan"**
10/25/2006	AMC/MSS	120	ORIG	10.00	0.40	10/25/2006	ALBC
11/24/2006	AMC/JEN	120	RFL001	10.00	0.40	11/25/2006	ALBC
12/26/2006	AMC/ALG	120	RFL002	10.00	0.40	12/26/2006	ALBC
01/22/2007	YYY/MSS	120	RFL003	10.00	0.40	01/24/2007	ALBC
02/21/2007	YYY/DLE	120	RFL004	10.00	0.40	02/22/2007	ALBC
03/20/2007	YYY/MSS	120	RFL005	10.00	0.40	03/23/2007	ALBC
04/19/2007	YYY/CLL	120	RFL006	10.00	0.40	04/23/2007	ALBC
05/21/2007	MSS/MSS	120	RFL007	10.00	0.40	05/26/2007	ALBC

Id. Each entry also contains a unique eighteen-digit numerical entry under a column labeled "Claim #." *Id.*

Entry Set Three

On the page of the Walgreens Records Bates-labeled "000016" (Doc. 81-3, p. 18), there is an entry row containing the following information:

- Under a column labeled "RX Number": "RX 0159402"
- Under a column labeled "Drug Name": "Metoclopramide 10 MG Tablets"
- Under a column labeled "Drug Mfr": "Purepac"
- Under a column labeled "Claim #": "10169501180208164l0"
- Under a column labeled "Doc Name": "Lauten, S"
- Under a column labeled "Orig Date": "03/02/2007"
- Under a column labeled "Qty": "120"
- Under a column labeled "Refills": "2"

- Under a column labeled "Days Supply": "0"

Id.

Headers at the top of all three pages of Walgreens Records—each page upon which an entry set appears— read "AL Walgreens Purged Data for Store 10169." (*See id.* at 12, 17, & 18).

The Target Records contain a number of entries mentioning "metoclopram," which, presumably, stands for metoclopramide. (*See* Doc. 81-4, pp. 7-10). However, none of these entries also refer to Actavis or Purepac. And although each page of the Target Records contains a column labeled "Drug NDC," no information is listed under this column in any of these records. (*See, e.g., id.).*

C. Conclusions of Law

The parties do not appear to dispute that Alabama's Extended Manufacturer's Liability Doctrine ("AEMLD") governs the claims that plaintiffs alleged in this case under the heading strict liability. (*Compare* Docs. 1, 81-1 & 85). The Eleventh Circuit has characterized the AEMLD as a "'fault-based defective product theory,' [] comparable to a defective product action grounded in strict liability" but "retain[ing] the negligence-based notion of 'fault' on the part of the manufacturer, supplier, or retailer." *Bodie v. Purdue Pharma Co., et al.*, 236 Fed. Appx. 511, 518 n. 9 (11th Cir. 2007) (per curiam).

The element of proximate cause is "essential" to establishing a *prima facie* case for both "AEMLD claim[s] . . . [and] negligent failure to adequately warn," *id.*, and "[p]roduct identification is an element of causation and a 'threshold requirement' in any products liability case," *Strickland v. Royal Lubricant Co., Inc.*, 911 F. Supp. 1460, 1470 (M.D. Ala. 1995) (*quoting Sheffiled v. Owens-Corning Fiberglass Corp.*, 595 So.2d 443, 450 (Ala. 1992)). Product identification evidence must

"afford . . . more than mere speculation, conjecture, or guess" in order to "warrant submission of the case to the jury." *See Turner v. Azalea Box Co.*, 508 So. 2d 253, 254 (Ala. 1987). However, a plaintiff may meet its causation burden under the AEMLD "through circumstantial as well as direct evidence." *Strickland*, 911 F. Supp. at 1470 (*quoting Sheffiled*, 595 So.2d at 450) (finding that "the inference drawn from circumstantial evidence is of sufficient strength to survive summary judgment on the causation issue." *Id.* at 1471)).

Actavis argues that the "[p]laintiffs cannot meet their threshold requirement—product identification—with the product records they submitted with their Initial Disclosures." (Doc. 81-1, p. 8). Actavis claims that "the[] records [plaintiffs produced] fail to adequately and sufficiently identify Actavis[] as the manufacturer of the metoclopramide Mrs. Mosley allegedly ingested between 2006 and 2007" because "the [Target] pharmacy records . . . provide neither a manufacturer name nor a[National Drug Code ("NDC")] number and [the Walgreens pharmacy records] provide a manufacturer name with no supporting information as to how, when or who entered that information." (*Id.*, pp. 6-9).

The plaintiffs do not appear to contest that the Target Records do not constitute evidence that Target dispensed metaclopramide produced by Purepac/Actavis to Mrs. Mosley. (See Doc. 35).

With respect to the Walgreens Records, Actavis specifically contends that

> there is no explanation or description regarding (1) who entered this information into Walgreens' system (i.e., whether it was the pharmacist who filled the prescription, an automated entry, or whether it was a data entry employee unfamiliar with the actual prescription dispensed); (2) how and based on what information the "Purepac" name was entered into Walgreens' system; and/or (3) when the manufacturer name was entered into the system (i.e., whether it was entered at the time the prescription was filled, when the records were purged from this particular store, or at some other point in time).

(Doc. 81-1, p. 7). In its reply brief, Actavis articulates even more "questions about the source, creation, and maintenance" of the Walgreens records, pointing to the "[p]urged [d]ata" header and claiming that "the 'Rx#' is included on some entries, but not others[,] there are seemingly duplicate entries on some dates; and . . . there is at least one questionable entry for a metoclopramide refill dispensed on a date weeks before it was due." *Id.*, p. 4.

It cannot be gainsaid that these questions, which apparently remain unanswered at this stage of the litigation, cast aspersion on the evidence that Walgreens dispensed metaclopramide produced by Purepac/Actavis to Mrs. Mosley. However, as noted above, "[i]n reviewing whether the nonmoving party has met its burden, the court must stop short of weighing the evidence . . . . Instead, the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Tipton*, 965 F.2d at 998-999; *see also Strickland*, 911 F. Supp. at 1470 ("purported [evidentiary] shortcomings [that] . . . go to . . . credibility and weight [constitute] questions properly left for the trier of fact at the trial on the merits. *Id.* (internal quotation and quotation marks omitted)). Drawing all justifiable inferences in the plaintiffs' favor, as the Court must at this juncture, the undersigned concludes that the plaintiff has presented evidence sufficient to allow a reasonable juror to conclude that Walgreens dispensed metaclopramide produced by Purepac/Actavis to Mrs. Mosley. Purepac/Actavis is not uniformly listed as the "Drug Mfr" for each of the entries in the Walgreens records produced. However, "Purepac" is clearly listed as the "Drug Mfr" in connection with each of the three entry sets for "Metoclopramide 10 MG Tablets" contained in Walgreens records. A reasonable juror could infer from this evidence that Walgreens dispensed Purepac/Actavis' metaclopramide to Mrs. Mosley. *See id.* at 1470 (the Federal Rules of Civil Procedure do not require "substantial evidence"). In particular, Entry Set Two, which contains the

most detailed data, suggests that Mrs. Mosley purchased metaclopramide produced by Purepac/Actavis in the quantities listed under the "Fill Qty" column on the corresponding dates appearing in the "Enter Date" or the "Fill Sold Date" columns.

The mere fact that the Walgreens records bear a "purged data" header does not warrant a grant of summary judgment in Actavis' favor. As noted above, Walgreens records custodian Tammy Irby submitted an affidavit indicating that "information contained in the records was transmitted to [her] in the regular course of business by Walgreens Pharmacy or an employee or representative of Walgreens Pharmacy who had personal knowledge of the information." Irby also stated under oath that the records "are . . . originals or exact duplicates of the original" records and were "made at or near the time or reasonably soon after the time that the service was provided." *Id.* The "purged" label does not provide reason to doubt Irby's sworn statements. Nor is the Court permitted on summary judgment to "make credibility determinations of the truth of the matter[s]" to which Irby attests. *See Tipton*, 965 F.2d at 998-999; *Strickland*, 911 F. Supp. at 1470.

Actavis implies that the metaclopramide Walgreens dispensed cannot be identified because the records lack an NDC number. Actavis points out that "[t]he Drug Listing Act of 1972 requires drug firms to list with the Food and Drug Administration [] prescription drug products manufactured, prepared, propagated, compounded, or processed by them for commercial distribution," and that "[i]f a drug firm does not list its marketed drug products properly with FDA, they are deemed misbranded and FDA can take enforcement action against the drug firm." *Id.* at 4. Actavis presents no evidence or argument suggesting that Walgreens Pharmacy is a "drug firm" within the meaning of the Drug Listing Act of 1972. As such, the Court has no basis upon which to conclude that the pharmacy was or is under any obligation to identify the products it dispenses

by using NDC numbers. In any event, as noted above, the evidence plaintiffs have produced is sufficient to permit a reasonable juror to conclude that Purepac/Actavis produced the metaclopramide that Walgreens dispensed to Mrs. Mosley.

In support of its arguments, Actavis cites *Enoch v. Firestone Tire & Rubber Co., et al.*, 534 So. 2d 266, 270 (Ala. 1988), and *Turner v. Azalea Box Co.*, 508 So. 2d 253, 254 (Ala. 1987). Both are distinguishable from the case at bar. In *Enoch*, the only product identification evidence produced on summary judgment was either based upon a hearsay statement or upon the plaintiff's affidavit, which "merely contradict[ed] without explanation[] previously clear testimony." *Enoch*, 534 So. 2d at 269. By contrast, the Mosleys have produced pharmacy records and an uncontradicted affidavit, on the basis of which a reasonable juror could conclude that Walgreens dispensed metoclopramide produced by Purepac/Actavis to Mrs. Mosley. *Turner* is likewise inapposite. In that case, the product at issue, wooden pallets, had "no distinguishing characteristics." *Turner*, 508 So. 2d at 254. A reasonable juror could conclude in this case, however, that certain of the Walgreens records clearly identified "Purepac" as the drug manufacturer of the metaclopramide that the pharmacy dispensed to Mrs. Mosley.

III. Conclusion

In accord with the foregoing, Actavis' motion for summary judgment is **DENIED.**

DONE this the **5th** day of **April, 2010.**

/s/ Kristi K. DuBose
KRISTI K. DUBOSE
UNITED STATES DISTRICT JUDGE