IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BRENDA LOUISE MORRIS,	*	
Plaintiff,	*	
v.	*	**Case No. BPG-13-1107**
MINNESOTA MINING AND MANUFACTURING COMPANY, et al.,	*	
Defendants.	*	

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MEMORANDUM OPINION

The above-referenced case was referred to the undersigned for all proceedings with the consent of the parties (ECF Nos. 20, 22), pursuant to 28 U.S.C. 636(c) and Local Rule 301.4. (ECF No. 16.) Currently pending is Defendants' Motion for Summary Judgment ("Motion") (ECF No. 39), plaintiff's Opposition to Defendants' Motion for Summary Judgment (ECF No. 45), Plaintiff's Memorandum of Grounds and Authorities in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment ("Opposition") (ECF No. 46), and Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (ECF No. 49). Oral argument was held before the undersigned on March 30, 2015. For the reasons discussed herein, Defendants' Motion for Summary Judgment (ECF No. 39) is GRANTED.

I. Background

The following is a summary of the evidence in this case, viewed in the light most favorable to plaintiff. In October 2007, plaintiff Brenda Louise Morris ("plaintiff")[1] was

[1] Plaintiff originally proceeded pro se, but is now represented by counsel. (ECF No. 37.)

prescribed Aldara cream[2] (hereinafter "Aldara") for treatment of Bowen's disease, a form of skin cancer which had manifested on plaintiff's nose. (Pl.'s Compl. ¶ 7, ECF No. 1 at 3; Pl.'s Resps. to Reqs. for Admis. Nos. 4 and 5, ECF No. 39-3 at 3.) Pursuant to her dermatologist's orders, plaintiff applied Aldara to her nose two times daily for a period of eight weeks. (Pl.'s Ans. to Interrogs. No. 2, ECF No. 39-4 at 2-3.) Shortly after plaintiff began applying Aldara to her nose, she developed burning lesions on her entire body. (Pl.'s Ans. to Interrogs. No. 7, Id. at 4.) Plaintiff sought medical attention and was ultimately diagnosed with severe cutaneous Lupus, which was determined to be proximately caused by plaintiff's use of Aldara. (ECF No. 39-5 at 15.) Plaintiff recently underwent neurological and neuropsychological testing which indicated that she also suffers from Posterior Reversible Encephalopathy Syndrome. (Kozachuk Aff. ¶ 7, ECF No. 46-2 at 2.) It was opined that this condition was also proximately caused by plaintiff's use of Aldara. (Kozachuk Aff. ¶ 9, Id.)

Aldara is currently approved by the United States Food and Drug Administration (hereinafter "FDA") for treatment of three conditions: (1) actinic keratosis, (2) superficial basal cell carcinoma, and (3) external genital warts. (ECF No. 46 at 2; Kavanaugh Aff. ¶ 6, ECF No. 39-1 at 3.) The use of Aldara to treat Bowen's disease is an "off-label" use, as Aldara has not been proven safe and effective in the treatment of that disease. (Pl.'s Compl. ¶ 19, ECF No. 1 at 11; ECF No. 39-5 at 8, 11-14.)

In November 2010, plaintiff sued her dermatologist for negligence and medical malpractice in the United States District Court for the District of Maryland, alleging that he breached the applicable standard of care by prescribing Aldara for an off-label use. (ECF No. 39-6 at 2-3.) Plaintiff's case was dismissed for lack of subject matter jurisdiction. (ECF No. 39-7 at 2-3.)

[2] Aldara is the trade name for a prescription drug called Imiquimod. (Kavanaugh Aff. ¶ 4, ECF No. 39-1 at 2-3.)

Thereafter, in December 2010, plaintiff filed suit against her dermatologist in the Circuit Court for Howard County, once again alleging that he breached the applicable standard of care by prescribing Aldara for an off-label use. (ECF No. 39-8 at 2-3.) Upon consideration of defendant's Motion to Dismiss, however, plaintiff's case was dismissed for failure to comply with the Maryland Health Claims Malpractice Act. (ECF No. 39-9 at 2; ECF No. 39-10 at 2-3.)

In October 2011, plaintiff once again filed suit against her dermatologist in the Circuit Court for Howard County. (ECF No. 39-11 at 3.) Plaintiff's First Amended Complaint not only asserted that defendant prescribed Aldara for an off-label use, but also acknowledged that the FDA and defendants warn against prescribing Aldara for off-label use due to the potential for severe side effects. (ECF No. 39-12 at 3.) The Circuit Court dismissed plaintiff's case in February 2012. (ECF No. 39-13 at 2.)

Plaintiff subsequently filed the instant lawsuit in April 2013 against (1) Minnesota Mining and Manufacturing Company, (2) Minnesota Mining and Manufacturing Company a/k/a 3M, (3) 3M Pharmaceuticals, a division of Minnesota Mining and Manufacturing Company, and (4) 3M Health Care Limited, asserting claims for negligence, negligence per se, product liability, breach of warranty, "conscious indifference," and malice. (Pl.'s Compl., ECF No. 1 at 1, 7-11.)[3] Plaintiff now alleges that defendants failed to provide adequate warnings concerning the risks, consequences, and side effects associated with the use of Aldara. (Pl.'s Compl. ¶¶ 7-9, 14, 16, Id. at 3-7, 9-10.) Further, plaintiff alleges that defendants warranted that Aldara was safe and effective for treating Bowen's disease when they knew it was not. (Pl.'s Compl. ¶ 19, Id. at 11.)[4]

[3] Defendants explain that "Minnesota Mining and Manufacturing Company" and "Minnesota Mining and Manufacturing Company a/k/a 3M" are the same entity, which should be referred to as "3M Company." (ECF No. 39 at 1.) Further, "3M Pharmaceuticals" is an internal division within 3M Company, rather than a separate entity. (Id.) The undersigned will refer to defendants collectively as "3M."

[4] The undersigned notes that plaintiff has changed the substance of her allegations since she filed suit against her doctor. Specifically, plaintiff previously alleged her doctor acted outside the standard of care, and in contravention

II. Summary Judgment Standard

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute remains "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is properly considered "material" only if it might affect the outcome of the case under the governing law. Id. The party moving for summary judgment has the burden of demonstrating the absence of any genuine issue of material fact. Fed. R. Civ. P. 56(a); Pulliam Inv. Co., Inc. v. Cameo Props., 810 F.2d 1282, 1286 (4th Cir. 1987). On those issues for which the non-moving party will have the burden of proof, however, it is his or her responsibility to oppose the motion for summary judgment with affidavits or other admissible evidence specified in Federal Rule of Civil Procedure 56. Fed. R. Civ. P. 56(c); Mitchell v. Data Gen. Corp., 12 F.3d 1310, 1315-16 (4th Cir. 1993). If a party fails to make a showing sufficient to establish the existence of an essential element on which that party will bear the burden of proof at trial, summary judgment is proper. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986).

When reviewing a motion for summary judgment, the court does not evaluate whether the evidence favors the moving or non-moving party, but considers whether a fair-minded jury could return a verdict for the non-moving party on the evidence presented. Anderson, 477 U.S. at 252. In undertaking this inquiry, the court views all facts and makes all reasonable inferences in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). The non-moving party, however, may not rest on its pleadings,

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of warnings provided by defendants and the FDA, by prescribing Aldara for an off-label use. Morris v. Pearson, No. 10-cv-03153-WMN (D. Md. dismissed Nov. 15, 2010); Morris v. Pearson, No. 10-C-10-085052 (Cir. Ct. Howard Cnty. dismissed Feb. 25, 2011); Morris v. Pearson, No. 13-C-11-88569 (Cir. Ct. Howard Cnty. dismissed Feb. 3, 2012).

but must show that specific, material facts exist to create a genuine, triable issue. Celotex, 477 U.S. at 324. A "scintilla" of evidence in favor of the non-moving party, however, is insufficient to prevent an award of summary judgment. Anderson, 477 U.S. at 252. Further, "mere speculation" by the non-moving party or the "building of one inference upon another" cannot create a genuine issue of material fact. Cox v. Cnty. of Prince William, 249 F.3d 295, 299-300 (4th Cir. 2001). Summary judgment should be denied only where a court concludes that a reasonable jury could find in favor of the non-moving party. Anderson, 477 U.S. at 252.

III. Discussion

Defendants contend that they are entitled to summary judgment on all claims asserted against them by plaintiff. (ECF No. 39 at 3.) Specifically, defendants argue that summary judgment is proper because: (1) plaintiff's claims are barred by the learned intermediary doctrine; (2) plaintiff's claims are barred by limitations; (3) plaintiff is asserting claims against the wrong defendant; and (4) plaintiff has no evidence to support the essential elements of her claims. (Id. at 9-14.) In her Opposition, plaintiff challenges each of these arguments. (ECF No. 46 at 4-8.) For the following reasons, the undersigned grants summary judgment in favor of defendants on all of plaintiff's claims.

A. Learned Intermediary Doctrine

First, defendants argue that they are entitled to summary judgment on the sole basis that plaintiff's claims are barred by the learned intermediary doctrine. (ECF No. 39 at 9; ECF No. 49 at 5.) Plaintiff, however, claims that the learned intermediary doctrine is not applicable to this case. (ECF No. 46 at 4.) Pursuant to the learned intermediary doctrine, drug manufacturers owe no duty to directly warn a patient of the risks associated with a particular drug, so long as the manufacturer has provided adequate warning to the prescribing physician. Lee v. Baxter

Healthcare Corp., 721 F. Supp. 89, 94-95 (D. Md. 1989). The physician is thus a "learned intermediary" between the manufacturer and the patient, because the physician is better positioned to determine the appropriate course of treatment for the patient. Id. at 95. The manufacturer is similarly under no obligation to warn the patient of risks associated with an off-label or non-indicated use of a drug and, therefore, cannot be held liable in the event the physician prescribes a drug for such use. Robak v. Abbott Labs., 797 F.Supp 475, 476 (D. Md. 1992). In fact, "when a physician decides to dispense an ethical drug for a condition for which it is not indicated, the manufacturer should not be held responsible for the consequences on *any* product liability theory under Maryland law." Id. (emphasis added).

Defendants assert that plaintiff's claims fail in accordance with Robak's reasoning because plaintiff's dermatologist prescribed Aldara for an off-label use; therefore, defendants cannot be held liable for any alleged consequences resulting from such use. (ECF No. 39 at 10.) Plaintiff attempts to distinguish Robak, arguing that plaintiff's injuries are not attributable to her dermatologist's off-label prescription of Aldara, but rather the inherently dangerous design of Aldara itself. (ECF No. 46 at 5.)[5] It is plaintiff's position, therefore, that even an "on-label" prescription of Aldara would have caused her alleged injuries. (Id.) Plaintiff claims that additional discovery would allow her to produce evidence demonstrating Aldara's defective design. (Id. at 5-6.)

This case is indistinguishable from Robak. Plaintiff has admitted, and the evidence of record confirms, that Aldara has not been approved for the treatment of Bowen's disease. (Pl.'s

[5] Defendants claim that plaintiff has changed the "gravamen" of her Complaint in responding to defendants' Motion. (ECF No. 49 at 3.) Specifically, defendants contend that plaintiff originally alleged her injuries were caused by defendants' failure to warn, but now alleges that they were caused by Aldara's inherently dangerous design. (Id.) Indeed, plaintiff did allege that Aldara is "a dangerously defective product" and "defective in design or formulation." (Pl.'s Compl. ¶¶ 15, 17, ECF No. 1 at 9-10.) As defendants note, however, Robak precludes holding defendants liable under any product liability theory. (ECF No. 39 at 8; ECF No. 49 at 5 (citing Robak, 797 F.Supp at 476).)

Compl. ¶ 19, ECF No. 1 at 11; ECF No. 39-5 at 8, 11-14; Kavanaugh Aff. ¶ 6, ECF No. 39-1 at 3.) Because plaintiff's dermatologist prescribed Aldara for an off-label use, defendants are not responsible for the alleged consequences of plaintiff's use of that drug. Further, plaintiff has failed to put forth any evidence, or identify with specificity what additional evidence exists, which could create a factual issue as to the defectiveness of Aldara. Nothing in plaintiff's expert affidavit (ECF No. 46-2 at 1-2) supports plaintiff's argument that her injuries were caused by the defective design of Aldara. Additionally, the fact that an "on-label" use of Aldara might have caused injuries similar to plaintiff's alleged injuries does not negate the application of Robak to the facts presented here. Accordingly, because plaintiff has failed to create a factual issue regarding the applicability of the learned intermediary doctrine, defendants' summary judgment motion is granted. Although summary judgment is justified on this basis alone, the undersigned will address defendants' remaining arguments.

B. Statute of Limitations

Defendants' second argument is that plaintiff's claims are barred by limitations because plaintiff had sufficient knowledge in October 2007 to suggest that she had a potential cause of action against defendants; however, plaintiff waited until April 2013, nearly five and a half years later, to file this lawsuit. (ECF No. 39 at 10-12.) In opposition, plaintiff argues that the limitations period did not commence until October 2011 when plaintiff was correctly diagnosed and became aware that her condition was related to Aldara. (ECF No. 46 at 7-8.)

Pursuant to Maryland law, "[a] civil action . . . shall be filed within three years from the date it accrues." MD. CODE ANN., CTS. & JUD. PROC. § 5-101 (West 2014). This three-year limitations period begins when the plaintiff "knew or reasonably should have known" of the alleged wrong. Pennwalt Corp. v. Nasios, 550 A.2d 1155, 1160 (Md. 1988) (internal quotation

marks and citation omitted). A plaintiff is regarded as having knowledge of an alleged wrong when the plaintiff "gains knowledge sufficient to prompt a reasonable person to inquire further." Id. at 1163. In Maryland, the temporal proximity between the use of a drug and the manifestation of injuries is sufficient to prompt a reasonable plaintiff to investigate. Quillin v. C.B. Fleet Holding Comp., Inc., 328 Fed.Appx. 195, 199-200 (4th Cir. 2009). If the plaintiff fails to investigate, however, she is nonetheless charged with the information that a reasonable investigation would have likely revealed. Pennwalt, 550 A.2d at 1162.

Plaintiff applied Aldara to her nose twice daily for an eight week period beginning in October 2007. (Pl.'s Resps. to Reqs. for Admis. No. 5, ECF No. 39-3 at 3; Pl.'s Ans. to Interrogs. No. 2, ECF No. 39-4 at 2-3.) Further, plaintiff has acknowledged that she began noticing symptoms, particularly, burning lesions on her entire body, within "days after taking [Aldara]." (Pl.'s Ans. to Interrogs. No. 7, Id. at 4.) Given the temporal proximity between plaintiff's use of Aldara and the alleged appearance of such lesions, plaintiff had sufficient knowledge in 2007 to be prompted to further investigate whether Aldara was responsible for her alleged injuries. Indeed, plaintiff did investigate, by seeking medical treatment immediately after her symptoms appeared. (Pl.'s Resps. to Reqs. for Admis. No. 3, ECF No. 39-3 at 3.) Plaintiff argues, however, that she was not properly diagnosed with severe cutaneous Lupus until 2011 (ECF No. 39-5 at 9, 15), and that her neurological symptoms were "never investigated" or "properly evaluated" until plaintiff was examined by Dr. Kozachuk in 2014. (Kozachuk Aff. ¶¶ 7-8, ECF No. 46-2 at 2; ECF No. 46 at 7.)

The fact that plaintiff's symptoms, neurological or otherwise, were not properly evaluated or diagnosed from the outset does not form a basis for tolling the limitations period. Plaintiff knew or should have known that Aldara might be responsible for her alleged injuries

when she initially experienced adverse symptoms and sought medical treatment in 2007. Therefore, the limitations period began to run at that time. See Quillin, 328 Fed.Appx at 199-200 (determining that plaintiff was on notice of possible wrongdoing because of the "proximity in time" of plaintiff's kidney failure to his colonoscopy procedure and ingestion of an over-the-counter medication) (internal quotation marks and citation omitted). Additionally, it should be noted that, according to plaintiff's expert, the labeling information for Aldara describes symptoms associated with its use which are comparable to those symptoms allegedly experienced by plaintiff. (ECF No. 39-5 at 4-7.) Because a reasonable investigation by plaintiff would have revealed this information, she is presumed to have had knowledge of it. In sum, there is no genuine issue of material fact that plaintiff had knowledge of her potential claims in 2007, but did not file the instant case until April 15, 2013, over five years later. Plaintiff's claims, therefore, are barred by limitations, and summary judgment for defendants is warranted.

C. 3M Is Not The Appropriate Party

Defendants contend that summary judgment is appropriate because plaintiff has sued the wrong party. (ECF No. 39 at 12.) Defendants assert that, in 2006, they sold their pharmaceutical operations in the United States, Canada, and Latin America to Graceway Pharmaceuticals, LLC (hereinafter "Graceway"). (Kavanaugh Aff. ¶ 3, ECF No. 39-1 at 2.) As a result of this transaction, Graceway acquired the exclusive rights to manufacture Aldara. (Kavanaugh Aff. ¶ 4, Id.) Since 2006, defendants have not marketed or sold Aldara to any consumers. (Kavanaugh Aff. ¶¶ 3-4, Id. at 2-3.) When plaintiff purchased Aldara in 2007, therefore, it was marketed and sold by Graceway. (Kavanaugh Aff. ¶ 4, Id. at 3.)

Plaintiff asserts that because Aldara was defectively designed, defendants remain liable to plaintiff as the original manufacturer pursuant to the Hatch-Waxman Amendments of the Food,

Drug and Cosmetics Act. (ECF No. 46 at 8.)[6] Plaintiff has failed, in both her Opposition and at oral argument, however, to offer any evidence to support the proposition that Aldara was defectively designed. Consequently, summary judgment for defendants is appropriate.

D. Summary Judgment Evidence

Defendants' final argument is that plaintiff has presented no evidence to support any of her claims in this case. (ECF No. 39 at 12.) Based upon a thorough review of the record, it is evident that plaintiff has not produced any evidence to show that "specific, material facts exist to create a genuine, triable issue." Celotex, 477 U.S. at 324.[7]

Plaintiff attempts to generate a material factual issue by offering the affidavit of Dr. Walter E. Kozachuk, and attachments. (ECF Nos. 46-2, 46-3, 46-5, 46-7, 46-9.)[8] An examination of Dr. Kozachuk's affidavit reveals, however, that it offers no evidence to support plaintiff's claims. The report contains no specific evidence that Aldara is defective, or that Aldara caused plaintiff's alleged injuries. Rather, the report merely contains the conclusory assertions, without evidentiary support, that plaintiff's neurological symptoms were "never

[6] The Hatch-Waxman Amendments provide an abbreviated application process for the approval of a generic drug by the FDA. 21 U.S.C.A. § 355(j) (West 2013). Because Aldara is not a generic drug, it is not apparent how those Amendments are pertinent here. Although plaintiff correctly states that pioneer and generic drug manufacturers must seek FDA approval prior to changing a drug product, plaintiff's claim that defendants remain liable because Graceway has not altered Aldara is without merit. 21 C.F.R. §§ 314.54, 314.70, 314.96, 314.97 (2015).

[7] As to plaintiff's negligence claim, plaintiff has not shown that defendants owed her a duty, that defendants breached that duty, or that there was a causal relationship between the alleged breach and the injuries suffered by plaintiff. See Schultz v. Bank of Am., N.A., 990 A.2d 1078, 1086 (Md. 2010). Plaintiff has failed to offer evidence that defendants violated a statute or ordinance designed to protect a class of persons including plaintiff or that plaintiff's injuries were proximately caused by the alleged violation, as is necessary to prove negligence per se. See Allen v. Dackman, 991 A.2d 1216, 1222-23 (Md. 2010). Nor has plaintiff produced any evidence that defendants sold Aldara, that Aldara was defective, that Aldara was unreasonably dangerous, or that the defective nature of Aldara proximately caused plaintiff's injuries in order to support her products liability claim. See Heckman v. Ryder Truck Rental, Inc., 962 F.Supp.2d 792, 802 (D. Md. 2013). Finally, plaintiff has no evidence to support her breach of warranty claim that Aldara was defective, that defendants are responsible for the defect, or that the defect proximately caused plaintiff's injuries. See Crickenberger v. Hyundai Motor Am., 944 A.2d 1136, 1143-44 (Md. 2008).

[8] Plaintiff has not even attempted to authenticate the attachments she offers in her Opposition. (ECF Nos. 46-5, 46-7, 46-9.) None of these unsworn, unauthenticated documents can be considered on a motion for summary judgment. Solis v. Prince George's Cnty., 153 F.Supp.2d 793, 798-99 (D. Md. 2001).

investigated," "never properly evaluated," and "show direct causation to the drug Aldara." (Kozachuk Aff. ¶¶ 7-9, ECF No. 46-2 at 2.) Such conclusory affidavits must be rejected by the Court when they represent nothing more than "an effort on the part of the plaintiff[] to create an issue of fact." Rohrbough v. Wyeth Labs., Inc., 916 F.2d 970, 976 (4th Cir. 1990). In sum, plaintiff has not offered any evidence warranting the denial of summary judgment for defendants.

Further, the undersigned concludes that plaintiff's attempt to defeat defendants' summary judgment motion by claiming she needs additional discovery must fail. Plaintiff argues that, in order to appropriately respond to defendants' Motion, she requires additional time to conduct discovery regarding her recently diagnosed neurological and neuropsychological conditions, as well as Aldara's allegedly dangerous design. (ECF No. 46 at 5-7.) Pursuant to Federal Rule of Civil Procedure 56(d), the Court may allow time to take discovery "[i]f a nonmovant shows by affidavit or declaration" that she cannot present facts to justify her opposition to a summary judgment motion. Fed. R. Civ. P. 56(d). Such a request for discovery may be denied, however, "where the additional evidence sought for discovery would not have by itself created a genuine issue of material fact sufficient to defeat summary judgment." Hamilton v. Mayor & City Council of Baltimore, 807 F.Supp.2d 331, 342 (D. Md. 2011) (internal citation omitted).

By letter order dated November 4, 2014, the court specifically invited plaintiff to make the requisite showing under Rule 56(d). (ECF No. 44.)[9] Plaintiff has failed to specifically

[9] Plaintiff filed a Motion to Modify Scheduling Order (the "Motion to Modify") on September 29, 2014, requesting to extend all deadlines in the Scheduling Order by ninety days to allow plaintiff to conduct additional discovery and designate additional expert witnesses. (ECF No. 38 at 1.) Defendants opposed the Motion to Modify, arguing that such an extension was unnecessary because no additional discovery could salvage plaintiff's claims. (ECF No. 40 at 1-5.) Defendants also requested (Id. at 4), and plaintiff agreed (ECF No. 43 at 3), to defer the undersigned's consideration of plaintiff's Motion to Modify until defendants' summary judgment motion was resolved. The undersigned deferred ruling on plaintiff's Motion to Modify, and gave plaintiff the opportunity to identify what additional discovery was necessary pursuant to Rule 56(d). (ECF No. 44.) As discussed above, because plaintiff has not presented evidence to establish any genuine issue of material fact, or that discovery is necessary before

identify, in accordance with Rule 56(d), what further discovery she requires, or what evidence that discovery would unveil. Indeed, at oral argument on the summary judgment motion, the undersigned specifically asked plaintiff's counsel to detail what additional evidence plaintiff needed before responding to defendants' Motion. Despite plaintiff's counsel's well-intentioned attempts, he was unable to do so. Accordingly, because plaintiff has not produced evidence sufficient to support the basic elements of her claims, defendants' Motion is granted.

IV. Conclusion

For the foregoing reasons, Defendants' Motion for Summary Judgment (ECF No. 39) is GRANTED. A separate order will be issued.

Date: 4/16/15

/s/
Beth P. Gesner
United States Magistrate Judge

plaintiff can oppose defendants' motion for summary judgment, it is not appropriate to extend the discovery deadline.