

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

STACY ZIMMERMAN,
personal representative of Phyllis Newman

Plaintiff

v.

**NOVARTIS PHARMACEUTICALS
CORPORATION**

Defendant.

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Case No.: RWT 08cv2089

MEMORANDUM OPINION

This pharmaceutical products liability lawsuit involves the drugs Aredia and Zometa, both of which were approved by the United States Food and Drug Administration (“FDA”) and are sold by defendant Novartis Pharmaceuticals Corporation (“Novartis”). On September 5, 2012, this Court entered an opinion and order granting a motion by Novartis to preclude any award of punitive damages. *See* ECF Nos. 166, 167. This matter is again before the Court on numerous other motions, including Defendant’s Renewed Motion for Summary Judgment. *See* ECF No. 174. The Court heard arguments with respect to all pending motions on November 1, 2012. As explained below, Defendant’s renewed motion will be granted, and all other pending motions will be denied as moot.

Procedural History

On September 29, 2005, Phyllis Newman was first named as a plaintiff in a products liability diversity class action brought against Novartis in the United States District Court for the Middle District of Tennessee. She was also named in a second amended complaint filed on November 28, 2005. Ms. Newman died in 2007. Following the death of Ms. Newman and the dismissal without prejudice of the class action, the Plaintiff, Stacy Zimmerman, as personal

representative of her estate, filed an individual products liability diversity action against Novartis in the United States District Court for the Middle District of Tennessee on December 5, 2007. Novartis is a Delaware corporation with its principal place of business in New Jersey. Ms. Newman was a resident of Maryland, as is her personal representative.

In her amended complaint, Plaintiff asserted strict liability and negligence claims against Novartis in connection with the manufacturing, distribution, promotion, testing, labeling and selling of Aredia and Zometa, two FDA approved bisphosphonate drugs which were approved for the treatment of patients with hypercalcemia of malignancy (a potentially fatal elevation of calcium in the blood), multiple myeloma, and breast cancer that has metastasized to bone. Ms. Newman, who was diagnosed with metastatic breast cancer to bone, was prescribed and received Aredia and Zometa in Maryland. As a result of her use of these drugs, she allegedly developed a jaw condition known as osteonecrosis (death of bone) of the jaw (“ONJ”).

On August 14, 2008, the United States District Court for the Middle District of Tennessee transferred the case under 28 U.S.C. § 1404 to this Court. On September 22, 2008, the Judicial Panel on Multidistrict Litigation issued a conditional transfer order transferring the case from this Court back to the Middle District of Tennessee for coordinated pretrial proceedings. On July 27, 2011, the Middle District of Tennessee advised the panel that coordinated pretrial proceedings had been completed and that the case should be remanded back to this Court.

Defendant first moved for summary judgment on May 19, 2011 while the case was still before the transferee judge in the multi-district litigation. *See* ECF No. 30. After remand from the transferee court and following a hearing held on October 31, 2011, that motion was denied by this Court as to the failure to warn claims on November 8, 2011. *See* ECF No. 93.

On September 18, 2012, after Plaintiff abandoned her previous theory of proximate causation [*See* Pl.’s Opp. to Mot. in Limine Regarding Dental Warnings (“Dental Warnings Opp.”), ECF No.146, at 5] and introduced two new causation theories [*See id.* at 2-4, and Pl’s Opp. to Mot. in Limine Regarding a Duty to Warn Doctors Other Than the Prescribing Physician (“Duty to Warn Opp.”), ECF No. 145, at 3], Defendant filed its Renewed Motion for Summary Judgment. *See* ECF No. 174. Plaintiff responded and also moved for leave to conduct additional discovery before responding. *See* ECF Nos. 186, 187. Defendant filed a reply, *see* ECF No. 189, and, as previously noted, the Court heard arguments on all pending motions on November 1, 2012. After the matter had been taken under advisement, and without obtaining leave of court to do so,¹ the Plaintiff filed a Supplement to her Response in Opposition to Defendant’s Renewed Motion for Summary Judgment, to which Novartis responded. *See* ECF Nos. 197, 198.

Background

Phyllis Newman was first diagnosed with breast cancer in 1987. *See* ECF No. 175 ¶ 1. Despite treatment, her cancer metastasized to her liver and bones by 1997. *Id.* at ¶ 2.

Dr. Marc Fisher, Ms. Newman’s periodontist, examined her in September 1997. *See* ECF No. 174, Ex. 2 ¶ 9; ECF No. 175 ¶¶ 14-16. He did not observe any problems with respect to her upper left third molar (tooth #16, commonly known as a “wisdom tooth”), which was impacted (*i.e.*, not erupted) at the time. *Id.* In December 1997, Ms. Newman visited her general dentist, Dr. Danoff, who also did not observe any issues with tooth #16, nor a need for any invasive dental procedures. *See* ECF No. 175, Ex. 13.

In January of 1998, Mrs. Newman’s oncologist, Dr. Frederick Smith, began prescribing her Aredia (later switched to Zometa in 2002) to prevent skeletal-related issues such as fractures

¹ Local Rule 105.2.(a) of this Court provides that “[u]nless otherwise ordered by the Court, surreply memoranda are not permitted to be filed.”

and bone pain. *See* ECF No. 175 ¶ 4; ECF No. 193, Ex. 1 ¶¶ 3-4. Dr. Fisher evaluated Ms. Newman again in February 1998, and still observed no issues with impacted tooth #16. *See* ECF No. 174, Ex. 2 ¶ 9; ECF No. 175 ¶ 14-16.

In June of 2001, Ms. Newman saw Dr. John Mennitt, an oral and maxillofacial surgeon, for problems that had arisen with tooth #16, which had by then erupted likely due to Mrs. Newman's age and the thinning of mucosa on that tooth. *See* ECF No. 175 ¶¶ 17, 18. The tooth was spontaneously exposed, was grossly decayed, and its extraction was unavoidable. *Id.* at ¶ 19. Dr. Mennitt recommended extraction which was carried out in July 2001. *Id.* at ¶¶ 17, 20. In August 2001, Dr. Mennitt observed a small sequestrum, or a piece of exposed bone, at the extraction site. *Id.* at ¶ 26. This exposed bone represented the onset of Ms. Newman's ONJ. *Id.* at ¶ 27.

In March of 2007, Ms. Newman died of metastatic breast cancer. *Id.* at ¶ 10.

DISCUSSION

I. Standard of Review on Summary Judgment

Summary judgment is proper if there are no issues of material fact and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Francis v. Booz, Allen & Hamilton, Inc.*, 452 F.3d 299, 302 (4th Cir. 2006). A material fact is one that "might affect the outcome of the suit under the governing law." *Spriggs v. Diamond Auto Glass*, 242 F.3d 179, 183 (4th Cir. 2001) (quoting *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986)). A dispute of material fact is only "genuine" if sufficient evidence favoring the non-moving party exists for the trier of fact to return a verdict for that party. *Anderson*, 477 U.S. at 248-49. However, the nonmoving party "cannot create a genuine issue of material fact through mere speculation or the building of one inference upon another." *Beale v. Hardy*, 769 F.2d 213,

214 (4th Cir. 1986). “A party opposing a properly supported motion for summary judgment ‘may not rest upon the mere allegations or denials of [his] pleadings,’ but rather must ‘set forth specific facts showing that there is a genuine issue for trial.’” *Bouchat v. Baltimore Ravens Football Club, Inc.*, 346 F.3d 514, 522 (4th Cir. 2003) (alteration in original) (quoting Fed. R. Civ. P. 56(e)).

The Court may only rely on facts supported in the record, not simply assertions in the pleadings, in order to fulfill its “affirmative obligation . . . to prevent ‘factually unsupported claims or defenses’ from proceeding to trial.” *Felty v. Grave-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987) (citing *Celotex*, 477 U.S. at 323-24). When ruling on a motion for summary judgment, “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Anderson*, 477 U.S. at 255. However, “if the evidence is merely colorable or not significantly probative, it may not be adequate to oppose entry of summary judgment.” *Thompson Everett, Inc., v. Nat’l Cable Adv.*, 57 F.3d 1312, 1323 (4th Cir. 1995).

II. Defendant’s Renewed Motion for Summary Judgment

In prescription drug cases alleging a failure to warn, the plaintiff is responsible for proving proximate causation—*i.e.*, that the inadequate warning “caused the injury.” *Ames v. Apothecan, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006). If “a warning would not have prevented the [injury],” then plaintiffs cannot “establish the causation element of their failure-to-warn claim, namely, that the absence or inadequacy of a warning was a proximate cause of the injury.” *Berger v. Ford Motor Co.*, 95 F. App’x 520, 522 (4th Cir. 2004).

Plaintiff originally alleged in her opposition to Defendant’s first motion for summary judgment that a “drug holiday” prior to the extraction of Ms. Newman’s tooth #16 would have prevented her jaw injury. *See* ECF No. 43 at 20-21. Noting that Dr. Smith has instituted such a

practice since hearing about the risk of invasive dental procedures in Aredia patients, Plaintiff argued that she had met her proximate cause burden. *Id.* Following the denial of Defendant's first motion for summary judgment, however, Plaintiff's two expert witnesses on causation admitted that there is no scientific evidence that a drug holiday actually reduces the risk of ONJ in Aredia patients undergoing invasive dental procedures. *See* ECF No. 138 at 4-5. Plaintiff has now abandoned the drug holiday theory. *See* ECF No. 146 at 5. Since then, Dr. Mennitt has also declared that when he saw Ms. Newman in June 2001, tooth #16 was "grossly decayed" and required immediate extraction, such that taking time for a drug holiday before extraction would not have been an option. *See* ECF No. 174, Ex. 1 ¶¶ 4-6.

Plaintiff now relies on two new theories to establish proximate causation:

- 1) If Ms. Newman's healthcare providers had known of the risk of invasive dental procedures in Aredia patients, she would have had a dental examination prior to starting Aredia and tooth #16 would have been extracted at that point; or
- 2) If Dr. Mennitt had known of the risk, he would not have extracted tooth #16 in 2001 while Ms. Newman was taking Aredia.

Plaintiff has offered largely speculative evidence to back up these theories. In support of her first "prior extraction" theory, Plaintiff's expert Dr. Richard A. Kraut has stated that the extraction of tooth #16 appears to have triggered the onset of Ms. Newman's ONJ. *See* ECF No. 146 at 4. He infers that had the tooth been extracted before Ms. Newman started taking Aredia and Zometa, ONJ would not have resulted. *Id.* Plaintiff's support for her second "alternative to extraction" theory consists entirely of Dr. Kraut's statement that "we would go to any length not to extract that tooth." *See* ECF No. 146 at 3.

Plaintiff's new theories are undermined by affidavits from two of Ms. Newman's healthcare providers, Dr. Mennitt and Dr. Fisher. *See* ECF No. 174, Exs. 1-2; ECF No. 193. Dr. Fisher states that it would have violated the standard of care to have removed a then-healthy tooth #16 in 1998 before Ms. Newman started taking Aredia. *See* ECF No. 174, Ex. 2 ¶ 10-11. Plaintiff herself concedes that Ms. Newman had a dental examination the month before she started on Aredia in 1998, and there were no issues with tooth #16 nor any problems that required an invasive dental procedure. *See* ECF No. 45 ¶ 26. Dr. Mennitt also declares that there was no treatment alternative three years later in 2001 to extracting tooth #16. *See* ECF No. 174, Ex. 1 ¶¶ 4-6. Dr. Kraut offered a similar assessment, conceding that "[a]t the time," tooth #16 "had to be extracted." ECF No. 175 ¶ 21.

On the basis of the facts currently before the Court, examined in the light most favorable to her, Plaintiff simply cannot prove that Defendant's alleged failure to warn was the proximate cause of Ms. Newman's jaw injury. Neither of Plaintiff's new proximate causation theories can withstand the facts asserted in Defendant's declarations. Defendant has provided uncontroverted evidence demonstrating that even if Defendant had warned of the risk of ONJ in Aredia/Zometa patients, Ms. Newman's tooth #16 would never have been extracted in 1998 before she started Aredia, and that it would have to have been extracted in 2001 while she was taking Zometa. Accordingly, summary judgment will be granted in favor of Novartis.

In granting Defendant's renewed summary judgment motion, this Court follows the example recently set by two other federal district courts ruling on similar cases arising from the same multi-district litigation. In *Eberhart v. Novartis Pharm. Corp.*, the court granted summary judgment to Novartis because the plaintiff could not meet her burden of proof on proximate causation. 2011 WL 5289372 (N.D. Ga. Oct. 31, 2011). The deciding fact in that case was an

affidavit from the treating endodontist stating that there were no alternatives to the tooth extraction which supposedly triggered the ONJ. In *Ingram v. Novartis Pharm. Corp.*, the court also granted summary judgment to Novartis on the causation issue. 2012 WL 2922716 at *6 (W.D. Okla. July 18, 2012). In that case, as here, the plaintiff failed to provide more than speculative evidence regarding whether a change in the prescribing oncologist's practices regarding Aredia and Zometa could have prevented the plaintiff's injury.

III. Plaintiff's Post-hearing Filings

As noted above, the Plaintiff filed a post-hearing "supplement" to her response to the Renewed Motion for Summary Judgment to which she attached a new affidavit of her expert, Dr. Richard A. Kraut. *See* ECF No. 197, Ex. 1. In paragraph 5 of his affidavit, he opines that in his "expert opinion, root canal would have been the preferable alternative to the extraction of Ms. Newman's Tooth #16, effected on July 25, 2001." *Id.* On the basis of this affidavit, Plaintiff contends that a genuine dispute of material fact has been generated that precludes an award of summary judgment. This Court does not agree.

First, the affidavit contradicts the May 4, 2011 deposition testimony of Dr. Kraut in which he then opined that there was no alternative to extraction, and that the tooth could not be saved. *See* ECF No. 189, Ex. 3 at 7. His latest position expressed in his new affidavit flatly contradicts his earlier deposition testimony and may be disregarded as a sham affidavit. Under the sham affidavit doctrine, "a party cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement (by, say, filing a later affidavit that flatly contradicts that party's earlier sworn deposition) without explaining the contradiction or attempting to resolve the disparity." *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806 (1999). Application of the sham affidavit rule at the summary judgment stage

“must be carefully limited to situations involving flat contradictions of material fact.” *Mandengue v. ADT Sec. Sys., Inc.*, No. ELH-09-3103, 2012 WL 892621, at *18 (D. Md. Mar. 14, 2012). This is one of those situations, and Dr. Kraut’s belatedly submitted new affidavit, being flatly contradictory to his deposition testimony, will not be considered.

Second, even if this Court were to consider his affidavit, it is insufficient to defeat summary judgment. The question before the Court is not what Dr. Kraut, a non-treating expert, thinks should or could have been done, but rather whether a warning by Novartis as to the risk of developing ONJ would have changed the treatment decision of Ms. Newman’s oral surgeon. It is undisputed that a warning would not have resulted in any such change. In his declaration, Dr. Mennitt, Ms. Newman’s treating oral surgeon, was unequivocal in stating as follows:

Given what I know today, that there is a possible association between ... [the drugs at issue in this case] ... and ONJ, I would still have treated Mrs. Newman the same, including the extraction of tooth #16. No additional information regarding the relationship between ONJ and ... [the drugs at issue] ... would have changed my treatment because tooth #16 had to be extracted immediately. *See* ECF No. 174, Ex. 1 ¶ 11.

Accordingly, the latest post-hearing filing of the Plaintiff, in a reversal of the usual formulation, is both too late and too little and will be disregarded.

IV. Plaintiff’s Motion for Additional Discovery

Rather than respond to the merits of Defendant’s renewed summary judgment motion, Plaintiff merely requests additional discovery under Federal Rule of Civil Procedure 56(d)² in the hopes of disputing the fatal facts set forth in the affidavit of Dr. Mennitt.³ *See* ECF No. 185.

² Plaintiff actually requests discovery under Rule 56(f). Under the revised Rule 56, the relevant portion of former subsection (f) is now contained in subsection (d). *See* Federal Rule of Civil Procedure 56.

³ Although Plaintiff mentions the declaration of Dr. Fisher as well as that of Dr. Mennitt in her motion and supporting affidavit, Plaintiff’s description of the discovery that she wishes to conduct relates only to Dr. Mennitt. *See* ECF No. 185 at 2-4. Dr. Fisher’s declaration wholly

Dr. Mennitt's affidavit contains two new facts which effectively undermine Plaintiff's theory that tooth #16 would not have been extracted in June 2001 if Defendant had warned of the risk of triggering ONJ in a patient on Aredia. These facts are that (1) there was no alternative treatment to the immediate extraction of Mrs. Newman's tooth in June 2001; and (2) even if Dr. Mennitt had known in June 2001 of an association between Aredia/Zometa and ONJ, he still would have extracted Mrs. Newman's tooth. *See* ECF No. 174, Ex. 1. In response to this declaration, Plaintiff seeks to discover what the bases are for Dr. Mennitt's opinion, whether additional x-rays of tooth #16 exist, whether Dr. Mennitt was aware of the risk of ONJ, and whether defense counsel somehow convinced Dr. Mennitt to offer these opinions. *See* ECF No. 186 at 3-4.

Initially, the Court finds no merit in Plaintiff's assertion that the "eleventh hour" appearance of these affidavits is somehow suspect or unfair. ECF No. 185 at 2-3. Plaintiff cannot legitimately claim to be surprised by the new information presented by Defendant. Plaintiff's own decision to switch proximate causation theories at this late stage of the case necessarily prompted Defendant to seek additional information to combat Plaintiff's claims. There is no reason to read the new declarations as indicative of some malicious design on Defendant's part, as Plaintiff suggests. There is also no evidence suggesting that defense counsel acted wrongly in obtaining the affidavits, or improperly influenced the content of the affidavits.⁴

negates Plaintiff's theory that tooth #16 could have been extracted before Ms. Newman started taking Aredia; Dr. Mennitt's declaration relates to Plaintiff's alternatives to extraction theory. By failing to address Dr. Fisher's statements, Plaintiff apparently concedes that she has no affirmative evidence to bolster her prior extraction theory, nor has any hope of obtaining such evidence.

⁴ Nor may the Court disregard the declarations as "sham affidavits" that contradict the affiant's prior testimony. *See Rohrbough v. Wyeth Laboratories, Inc.*, 916 F.2d 970, 975 (4th Cir. 1990). The fact that some of the information set forth in Dr. Mennitt's declaration was not elicited during his deposition does not make it any less relevant or truthful. Defendant deposed Dr.

Furthermore, Plaintiff has not satisfied the Rule 56(d) standard for granting additional discovery. Federal Rule of Civil Procedure 56(d) provides that the non-moving party to a summary judgment motion may obtain a continuance to conduct discovery upon a showing by affidavit that it is lacking essential facts needed to justify its opposition. Such a motion is only appropriate in situations where the discovery sought could not have been obtained during the course of normal discovery. *See CBRE Realty Fin. TRS, LLC v. McCormick*, 414 F. App'x 547, 551 (4th Cir. 2011). The motion must be accompanied by an affidavit that “specif[ies] the reasons the party is unable to present the necessary facts and describe[s] with particularity the evidence that the party seeks to obtain”; an affidavit that “conclusorily states that discovery is required is insufficient.” *Radi v. Sebelius*, 434 F. App'x 177, 178 (4th Cir. 2011); Fed. R. Civ. P. 56(d). A Rule 56(d) motion will be denied “where the additional evidence sought for discovery would not have by itself created a genuine issue of material fact sufficient to defeat summary judgment.” *Strag v. Bd. of Trs., Craven Cmty. Coll.*, 55 F.3d 943, 954 (4th Cir. 1995).

First, there is no need for additional discovery in this case. This lawsuit has been pending for over seven years and has been before this Court since 2008, when it was transferred here from the Middle District of Tennessee. *See* ECF No. 8. The parties already have gone through extensive discovery as part of the larger, multi-district litigation process. *See* ECF No. 2. The parties have also engaged in additional discovery after the case was remanded to this Court from

Mennitt on January 11, 2011. *See* ECF No. 186 at 2. At that time, Plaintiff was operating under the “drug holiday” theory of proximate causation. There was no need for Defendant to question Dr. Mennitt about alternative treatments to extraction or what he would have done differently (if anything) had he known about the Aredia-ONJ connection. If a witness was never actually asked in his deposition about information which he later offered in an affidavit, that affidavit should not be considered a sham. *See Servicios Especiales al Comercio Exterior v. Johnson Controls, Inc.*, 2011 WL 1498591, at *3 (E.D. Wis. April 19, 2011).

the MDL transferee judge. Fact discovery had closed before Defendant filed its renewed summary judgment motion.

All of the information Plaintiff now seeks could have been obtained during the normal course of discovery. Plaintiff bears the burden of demonstrating proximate causation, and thus also carries the responsibility for developing facts to support this element of her case. Plaintiff did not question Dr. Mennitt at his deposition about any of the opinions that he expressed, nor did Plaintiff inquire into areas that were not addressed during the deposition. If Plaintiff wanted to question Dr. Mennitt about the opinions expressed in his affidavit, then she should have contacted him and secured a declaration or affidavit, just as Defendant did. Plaintiff and Defendant have equal access to Dr. Mennitt. Defendant was able to acquire an affidavit from the doctor to support its renewed motion for summary judgment; there is no reason why Plaintiff could not have done the same. Plaintiff's own lack of diligence and foresight, not a lack of opportunity, is to blame for her dearth of affirmative evidence. *See CBRE Realty*, 414 F. App'x at 551 (Rule 56(f) motion was properly denied where appellants were not diligent in pursuing their discovery rights during the discovery period). Plaintiff simply cannot claim that insufficient discovery was provided in this case. *See Ladson v. Thompson*, 2003 WL 22889793, at *3 (D. Md. Dec. 3, 2003) (rejecting plaintiff's Rule 56(f) motion in part because the race discrimination complaint had been investigated at the administrative level, resulting in a wealth of available information and negating the need for additional discovery). This is especially so in light of the fact that the proposed additional discovery claimed to be necessary results from the Plaintiff's change in theories of recovery virtually on the eve of a scheduled trial.

Second, Plaintiff's motion and supporting affidavit do not identify any specific facts that could be obtained through additional discovery that would enable her to defeat Defendant's

summary judgment motion. Plaintiff lists a series of questions she wishes to ask Dr. Mennitt, but does not identify a single piece of information that she expects those questions to produce that would enable her to bring her case before a jury. She also suggests that looking at additional x-ray films might enable her expert, Dr. Kraut, to opine that there was an alternative to extracting tooth #16. But the idea that another set of films exists is pure speculation. Rule 56(d) does not allow parties to engage in a “fishing expedition,” especially one proposed after seven years of litigation. *Morrow v. Farrell*, 187 F. Supp. 2d 548, 551 (D. Md. 2002), *aff’d*, 50 F. App'x 179 (4th Cir. 2002). Courts may reject a motion for additional discovery if the request is based on speculation and “the mere hope that something might turn up in further discovery.” *Young v. UPS*, 2011 WL 665321, at *21 (D. Md. Feb. 14, 2011). Here, Plaintiff has failed to indicate that additional discovery would produce any concrete facts to bolster her case. Therefore, Plaintiff’s Rule 56(d) motion will be denied.

V. Defendant’s Motions in Limine

Defendant has filed numerous motions in limine concerning evidentiary and other pre-trial issues. *See* ECF Nos. 127, 131, 132, 134, 135, 138 and 194. These motions are now moot in light of the summary judgment ruling, and accordingly will be denied as moot.

VI. Plaintiff’s Motion for Interlocutory Appeal

Finally, Plaintiff seeks permission to file an interlocutory appeal of this Court’s punitive damages ruling. *See* ECF No. 183. This motion is also now moot in light of the summary judgment ruling, and accordingly will be denied as moot.

CONCLUSION

For the foregoing reasons, the Defendant's Renewed Motion for Summary Judgment will, by separate order, be granted and all other pending motions will be denied as moot.

Date: November 15, 2012

/s/
ROGER W. TITUS
UNITED STATES DISTRICT JUDGE