IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SUSAN EBERHART, **Plaintiff,** **v.** **NOVARTIS PHARMACEUTICALS CORPORATION,** **Defendant.**	**1:08-cv-2542-WSD**

OPINION AND ORDER

This matter is before the Court on Defendant Novartis Pharmaceuticals Corporation's ("NPC") Renewed Motion for Summary Judgment [39] and Plaintiff Susan Eberhart's ("Plaintiff") Motion to Strike Declaration of Dr. Randall A. Coggins, DMD, MS [52].

I. BACKGROUND

In this pharmaceutical products liability action, Plaintiff claims she was injured by NPC's failure to warn her or her oncologist about a purported increased risk of osteonecrosis of the jaw ("ONJ," essentially dying bone in the jaw) associated with two drugs that NPC manufactures. Plaintiff was prescribed the medication to treat recurrent breast cancer that had metastasized to her sternum.

She contends that had NPC properly warned about the risk of ONJ created by its drugs, she would not have allowed for three of her teeth to be extracted during the course of her cancer treatment and would have elected endodontic treatment instead. She alleges the extractions caused her to develop ONJ. NPC argues that any alleged failure to warn was not the proximate cause of Plaintiff's injuries because endodontic treatment was not a treatment option for the dental conditions that required Plaintiff's extractions and because the extractions were the only treatment option for Plaintiff. Thus, NPC claims, even if it had given an ONJ warning, the extractions still were required to be performed.

Plaintiff's Aredia And Zometa Treatments

Plaintiff suffers from breast cancer that was originally diagnosed in February 1987 and that, after remission, recurred in February 2001. (NPC's Statement of Material Facts ("DSMF") [39-8] ¶¶ 1-2; Pl.'s Response to NPC's Statement of Material Facts ("RDSMF") [61] ¶¶ 1-2). In February 2001, Plaintiff's oncologist, Dr. Galleshaw, diagnosed bone metastases on Plaintiff's sternum. (DSMF ¶ 3; RDSMF ¶ 3). Beginning in March 2001, Dr. Galleshaw prescribed to Plaintiff monthly doses of Aredia, which NPC manufactures.[1] (DSMF ¶ 6; RDSMF ¶ 6).

[1] Generic forms of Aredia were available at the time Dr. Galleshaw prescribed Aredia to Plaintiff. The record is unclear whether Plaintiff received Aredia or a generic substitute but that is irrelevant to the present motions.

Aredia is a type of drug known as a bisphosphonate and is FDA-approved for the treatment of breast cancer that has metastasized to the bones. (DSMF ¶¶ 10, 12; RDSMF ¶¶ 10, 12). Aredia is also FDA-approved to treat hypercalcemia of malignancy. (DSMF ¶ 11; RDSMF ¶ 11). Hypercalcemia of malignancy is a potentially fatal elevation of calcium levels in the blood, which results either when the cancer causes direct loss of bone that elevates the amount of calcium in the blood, or when the cancer triggers other processes that cause elevations of calcium levels without accompanying bone loss. (Galleshaw Dep. 13:17-23, 14:21-25).

By December 2001, despite the Aredia treatment, Plaintiff developed hypercalcemia and her health significantly deteriorated. (DSMF ¶¶ 6, 20-21; RDSMF ¶¶ 6, 20-21). Dr. Galleshaw changed Plaintiff's treatment regimen from Aredia to Zometa, which NPC also manufactures. (DSMF ¶ 6; RDSMF ¶ 6). Like Aredia, Zometa is a bisphosphonate that is FDA-approved for the treatment of bone metastases of breast cancer and hypercalcemia of malignancy. (DSMF ¶¶ 13-14; RDSMF ¶¶ 13-14). After starting the Zometa treatment, Plaintiff's hypercalcemia immediately improved and she remains alive. (DSMF ¶ 22; RDSMF ¶ 22). Plaintiff continued receiving monthly infusions of Zometa until December 2004. (DSMF ¶ 7; RDSMF ¶ 7). There is no evidence that Plaintiff or Dr. Galleshaw knew or were warned of any connection between bisphosphonates

and ONJ during the course of Plaintiff's treatment, until Dr. Galleshaw received a letter from NPC in September 2004 noting reports of a possible connection. (Pl.'s Statement of Additional Material Facts ("PSMF") [61] ¶ 1; Def.'s Resp. to PSMF ("RPSMF") ¶ 1).

Plaintiff's Tooth Extractions And Subsequent Complications

In July 2002, Plaintiff reported a "stabbing pain" in some of her teeth and was referred by her dentist to Dr. Randall Coggins, an endodontist. (DSMF ¶ 26; RDSMF ¶ 26). Dr. Coggins examined Plaintiff on July 8, 2002. (Dr. Coggins's Records for Susan Eberhart, Coggins Decl. ¶ 4, Ex. 1). Dr. Coggins observed that tooth "#18 [is] mobile – seems to be perio in nature." (Id. at 8). Dr. Coggins drafted a report for Plaintiff's referring dentist. The report is on a form that lists potential diagnoses and treatment outcomes, and provides space for Dr. Coggins to mark the options that apply in a specific case. In the report, Dr. Coggins indicated that he had examined teeth numbers 18, 19, and 20. (Id. at 9).[2] The report notes that Plaintiff's teeth "Tested within normal limits to clinical tests," but that there was "periodontal pocketing" with respect to "[tooth] #18." (Id.). Discussing the

[2] Teeth numbers 18, 19, and 20 were the three rear-most teeth on the bottom left side of Plaintiff's mouth. (Plaintiff's wisdom teeth had been extracted previously.) With the wisdom tooth gone, tooth 18 was the rear-most molar on the bottom left side of Plaintiff's mouth. Tooth 19 was the molar in front of tooth 18. Tooth 20 was the bicuspid in front of tooth 19.

treatment recommendations for Plaintiff, Dr. Coggins stated that "Endodontic treatment is not indicated at this time," and recommended "Periodontal evaluation/treatment" for "gingivitis/periodontitis." (Id.). Although "Extraction" was a treatment recommendation listed on the form, Dr. Coggins did not indicate that option. (Id.). Dr. Coggins referred Plaintiff to the office of Dr. Allen French and Dr. Virginia Kirkland, who are both periodontists. (Id. at 10). The referral form asked Drs. French and Kirkland to evaluate Plaintiff's periodontal condition. (Kirkland Dep. Exs. at 0061-0015). Under the section entitled "Special Problem Areas Limited To," which contained a diagram of teeth numbers, Dr. Coggins circled tooth 18. (Kirkland Dep. Exs. at 0061-0015).

On July 11, 2002, Plaintiff visited Dr. Kirkland for a periodontal examination.[3] (Kirkland Dep. 46:6-7). Dr. Kirkland diagnosed Plaintiff with "isolated severe periodontal disease" around teeth 18, 19, and 20. This disease is unrelated to Plaintiff's cancer and is not caused by the medications manufactured by NPC and prescribed for Plaintiff by Dr. Galleshaw. (Id. at 33:25). According

[3] The parties do not discuss the distinction between endodontic and periodontal examinations. Dr. Kirkland mentioned the difference briefly during her deposition: "I wasn't sure what the cause of the infection was . . . . Dr. Coggins saw her and indicated that it was not an endodontic problem. There's only two places really that an infection around a tooth can come from: one's from the tooth itself, which would be an endodontic consult; the other is from the periodontium, that's me. So [Dr. Coggins] ruled out the tooth and sent her to me because it was gum." (Kirkland Dep. 31:14-24).

to Dr. Kirkland, her examination revealed two factors indicative of periodontal disease: pocketing and mobility. (Id. at 29:8-15, 30:24-31:6). Pocketing refers to the loss of attachment between the gum and tooth; ratings of 1 to 3 are considered normal while 6 denotes a severe loss of attachment. (Id. at 29:8-30:7). A mobility classification of 1 is considered moderate, while class 2 or 3 is consistent with severe periodontal disease. (Id. at 30:24-31:6, 43:7-9, 80:20). Plaintiff's tooth 18 had pocket measurements in the 5s and 6s and class 2 to 3 mobility. (Id. at 30:21-23; 43:7-9). Tooth 19 did not display significant pocketing, but Dr. Kirkland testified that "even though 19 is not pocketing, it's got a Class 2 mobility. So something's going on there, too." (Id. at 31:4-6). Dr. Kirkland also testified that tooth 20 appeared to be healthy, although it had class 1 mobility. (Id. at 59:2-4, 80:20).

Tooth 18 was also abscessed, and Dr. Kirkland's July 11, 2002, treatment focused on tooth 18.[4] (Id. at 46:4). Dr. Kirkland testified that she "did an I&D, which is an incise and drain; it's treatment for an abscessed tooth. Also, at the same time we did scaling and root planing for the other areas of pocketing. Scaling and root planing, all of this is a non-surgical type of a treatment done specifically to reduce the number of bacteria in these deep pockets. If enough of

[4] Plaintiff describes an abscess as "a severe infection periodontally between the tooth and gum around the roots. (Pl.'s Resp. Mot. Summ. J. 5).

the bacteria is removed—also, placed her on an antibiotic, too—these together will encourage healing of the area so that I could better evaluate what to do." (Id. at 46:13-23).

A week later, on July 31, 2002, Dr. French extracted tooth number 18. (Id. at 34:21). Dr. Kirkland testified that tooth 18, due to periodontal disease, could not be saved and extraction was required. (Id. at 43:10-15). Dr. Kirkland's decision to extract tooth 18 would not have been different even if she had known of a connection between Aredia/Zometa and ONJ. She testified: "[W]hen you have an abscessed tooth and a patient in pain, you really don't have a lot of options. If the tooth has to come out, the tooth has to come out. I covered her with antibiotics. I don't think I would have treated her any differently." (Id. at 72:16-24).

On August 13, 2002, Dr. Kirkland extracted teeth numbers 15 and 19. Tooth 15 was above the site of previously-extracted tooth 18, and "the tooth above is usually extracted at the same time for balance, because 15 needs something to bite against or oppose." (Id. at 35:16-21). There was also some decay around tooth 15. (Id. at 35:23).

Tooth 19 was removed because Plaintiff was complaining of a throbbing pain. (Id. at 36:16; Medical record dated Aug. 13, 2002, DSMF Ex. 26). Dr. Kirkland testified that tooth 19 was significantly mobile and that she agreed

with Dr. Coggins's initial diagnosis that the problem was periodontal in nature rather than endodontic. (Kirkland Dep. 31:4-32:6). Nevertheless, after the extraction of tooth 18, Dr. Kirkland "tried to get [Plaintiff] to go back and see Dr. Coggins, but she did not want a root canal or to even talk with Dr. Coggins about it, so she wanted 19 removed." (Kirkland Dep. at 26:16-19). Dr. Kirkland specifically discussed with Plaintiff the possibility of trying to retain tooth 19. (Id. at 20-22). In her deposition testimony, however, Dr. Kirkland does not state that she thought endodontic treatment was a viable treatment option or that tooth 19 could be saved.

On April 10, 2003, Plaintiff had a follow-up visit at Dr. Kirkland's office. (Id. at 37:20-21). Reviewing the records from that visit, Dr. Kirkland testified that everything regarding the tooth 18 and tooth 19 sites "was within normal limits. Everything healed beautifully." (Id. at 38:11-12). Plaintiff complained during that visit about pain around tooth 20. (Id. at 38:17-19).

By August 2003, Plaintiff was experiencing swelling in her jaw in the area of the tooth extractions. On August 22, 2003, Plaintiff visited Dr. Kakos, an oral surgeon. (Kakos Dep. at 6:16-30). Dr. Kakos scheduled a second appointment for August 27, 2003, to perform an incision and drainage of the infected site. (Id. at 55:23-56:4). During the August 27 treatment, prior to making the incision opening

for the incision and drainage procedure, Dr. Kakos observed exposed bone. (Id. at 86:7-10). Dr. Kakos "flapped and exposed the area and . . . removed a small piece of bone that was there at that time." (Id. at 56:6-8). To "flap and explore" means to "mov[e] the tissue out of the way," or to "remove[] the gum tissue out of the way just to be sure that there wasn't any additional infection in [the] area." (Id. at 88:9-22). Dr. Kakos also removed a little bone from that area where teeth 18 and 19 had been, in order to biopsy it for cancer metastases. (Id. at 58:12-15, 88:17-21). The biopsy ruled out cancer metastases but indicated fragments of dead bone in that area. (Id. at 59:2-3, 85:19-23).

On September 4, 2003, Plaintiff complained to Dr. Kakos about pain in the area of tooth 20. (Id. at 53:17-19). Dr. Kakos wanted to refer Plaintiff to Dr. Coggins for endodontic treatment of tooth 20, but Plaintiff indicated that she did not want to have a root canal done and preferred to have the tooth extracted. (Id. at 53:21-24). Dr. Kakos is a strong advocate of root canals and other methods to retain patients' natural teeth, often "spend[ing] an inordinate amount of time with the patient" to convince them to seek endodontic treatment such as a root canal, and he is certain that he had such a conversation with Plaintiff. (Id. at 54:8-22).

On September 7, 2003, Plaintiff went to Dr. Kirkland to have tooth 20 extracted. Dr. Kirkland discussed Plaintiff's tooth number 20 with Dr. Kakos, and

Dr. Kakos testified that they both "felt that . . . the x-ray . . . [did] not show any massive abscess of the tooth," and that they "wanted to refer it to Dr. Coggins for . . . evaluation for endodontics for a root canal." (Id. at 53:7-13). Dr. Kirkland also attempted to refer Plaintiff to Dr. Coggins for an endodontic consultation. (Kirkland Dep. 37:4-7). She testified: "The reason that tooth was taken out was not a periodontal issue. It was an abscess, but I don't think it was of the periodontal origin and . . . the tooth could have been saved with a root canal, in my opinion. . . . But she was not interested, did not want a root canal, was not interested in saving in. The tooth hurt, she wanted it out." (Id. at 80:22-81:5). On September 12, Dr. French extracted tooth number 20. (Id. at 37:5).

On September 18, 2003, Plaintiff returned to Dr. Kakos, who reported at the time that the "[e]xtraction site looks great" in the area of tooth 20. (Kakos Dep. 64:13-65:6). He also did not observe any exposed bone in the area of tooth 18 or tooth 19. (Id.). On October 14, 2003, Plaintiff had a follow-up appointment with Dr. French, who observed an osseous sequestrum at the number 19 site, as well as a fistula. (Dr. Kirkland's medical record for Susan Eberhart, DSMF Ex. 28). Dr. Kirkland described an osseous sequestrum as an area where the tissue is so thin that it exposes the bone underneath or, in other words, "basically exposed bone."

(Kirkland Dep. 74:7:-13).[5] Dr. Kirkland performed another examination on October 22, 2003, and noted that the sequestrum was still present but not the fistula. (DSMF Ex. 28). During appointments through the remainder of October and through November and December, Drs. French and Kirkland noted that the sequestrum around the tooth 19 extraction area was healing very slowly and that the fistula had reappeared. (Id.).

On December 15, 2003, Plaintiff called Dr. Kakos to complain of additional complications in the area of the tooth extractions. (Dr. Kakos's Records for Susan Eberhart, Kakos Dep. Ex. 4). On December 18, 2003, Dr. Kakos examined Plaintiff and observed a festering fistula in the area of the tooth 19 extraction and exposed bone on the lingual (tongue) side of her gums. (Id. at 90:2-4 & Ex. 4). Because of the increasing complexity of Plaintiff's case, Dr. Kakos referred Plaintiff to Dr. Meyer, an oral surgeon with dual degrees in medicine and dentistry. (Id. at 67:2-68:3).

Dr. Meyer treated Plaintiff from December 2003 until approximately December 2004. (Meyer Dep. 43:16-22). Plaintiff had exposed bone on her jaw during that entire time, in the general area where tooth number 19 had been. (Id. at 56:11-15, 57:8-16). Dr. Meyer initially suspected that Plaintiff had osteomyelitis,

[5] A fistula is a small site that looks similar to a pimple. A festering fistula means the fistula is draining. (Kakos Dep. 90:9-11).

which is an infection of the bone marrow. (Id. at 37:12-14, 69:20-21). Dr. Meyer had heard of a possible connection between bisphosphonates and ONJ and learned during Plaintiff's treatment that she was taking bisphosphonates. (Id. at 57:23-58:19, 59:16-25). Dr. Meyer did not definitively diagnose Plaintiff with ONJ, but based on her history of chemotherapy and her bisphosphonate infusions, Dr. Meyer undertook a conservative treatment regimen to avoid making Plaintiff's condition worse. (67:19-70:10).

Dr. Roser, an oral surgeon at Emory University, treated Plaintiff from March 2005 until July 2009. (Roser Dep. 19:11-13, 27:8-16). Dr. Roser concluded that Plaintiff's "history, appearance, [and] condition," were consistent with ONJ, and, based on his understanding of the link between Aredia/Zometa and ONJ, he did not investigate other causes of Plaintiff's exposed bone. (Id. at 33:16-34:5). On July 7, 2005, Dr. Roser performed surgery, removing the dead bone from Plaintiff's jaw. (Id. at 24:2-25). As of July 2009, Plaintiff was fully healed and no longer had any exposed bone. (Id. at 27:8-22).

Plaintiff's Oncologist Learns Of Reported Increased Risk of ONJ

In approximately September 2004, Plaintiff's oncologist, Dr. Galleshaw, received from NPC a "Dear Doctor" letter dated September 24, 2004, disclosing a reported association between Aredia/Zometa and ONJ. (PSMF ¶ 1; RPSMF ¶ 1).

This was the first Dr. Galleshaw had heard of this connection. (Galleshaw Dep. 87:21-24).

In December 2004, Dr. Galleshaw met with her practice group's clinical research and therapeutics committee to discuss the potential link between bisphosphonates and ONJ. (Galleshaw Dep. 20:15-21:12). Sometime after the meeting, the group developed a handout for patients warning of the potential risk of ONJ and telling patients something to the effect that "invasive dental procedures should be avoided during treatment." (Id. at 32:21-33:18, 85:10-22). Dr. Galleshaw testified that after December 2004 she discusses with patients receiving bisphosphonates the risk caused by invasive dental procedures and that she discusses their dental health and warns them to let her know about invasive procedures in advance so that they can avoid "wound-healing complications." (Id. at 85:16-86:4). In December 2004, after learning of Plaintiff's jaw issues and the reported association between bisphosphonates and ONJ, Dr. Galleshaw, as a precaution, discontinued Plaintiff's Aredia/Zometa treatments. (Id. at 66:8-14, 78:15, 79:25-80:16).

Despite changing the warnings she gives to patients after December 2004, Dr. Galleshaw considers Aredia and Zometa the "standard of care" for patients such as Plaintiff. (Galleshaw Dep. 50:11-13). Had Dr. Galleshaw known of the

connection between bisphosphonates and ONJ in 2001, she still would have prescribed Aredia/Zometa infusions for Plaintiff. (Id. at 50:14-19). Dr. Galleshaw has not changed the dosage or duration for which she prescribes Aredia/Zometa to her patients, and in some cases she prescribes more than the recommended dosage. (Id. at 15:6-10, 88:11-89:15).[6] She acknowledges that some doctors "arbitrarily after two or three years discontinue[] the drug," but that is not her practice. (Id.).

Plaintiff asserts that had she been warned of the increased risk of ONJ, she would have heeded the advice of Dr. Kirkland and Dr. Kakos and would have undergone endodontic treatment for teeth numbers 19 and 20. She testified: "I opted to have the teeth extracted because of my apprehension of dental procedures since I was a child and costs. Had I been warned that having my teeth extracted would expose me to a risk of osteonecrosis of the jaw that was greater than the risk posed by endodontic treatment, I would have undergone endodontic treatment for teeth nos. 19 and 20." (Eberhart Decl. dated Aug. 24, 2010 [39-6]).

Dr. Coggins, the only endodontist who has offered testimony in this action, "would not have performed any endodontic treatment on [Plaintiff's] teeth #'s 18, 19 and 20 because in [his] professional opinion those teeth tested normal from an

[6] This is her practice except for patients with kidney problems, which did not apply to Plaintiff.

endodontic perspective, and endodontic treatment was therefore not a viable treatment option for those teeth." (Coggins Decl. dated Apr. 27, 2011 [39-7]).

Procedural Background

This action was originally filed as a class action in the United States District Court for the Middle District of Tennessee, Nashville Division. That Court denied class action certification and Plaintiff filed her Amended Complaint, asserting claims for strict product liability, negligence, and negligence per se. (See Am. Compl. [1]). On August 5, 2008, the Tennessee District Court transferred Plaintiff's case to this Court, but suggested that the plaintiffs in the Aredia/Zometa litigation petition the Judicial Panel on Multidistrict Litigation to transfer the case back to Tennessee for consolidated pretrial proceedings. On September 23, 2008, this action was transferred to the Middle District of Tennessee for multidistrict proceedings. In re Aredia & Zometa Prods. Liab. Litig., No. 3-06-MD-1760 (M.D. Tenn.) ("MDL Court").

On August 2, 2010, NPC moved in the MDL Court for summary judgment on all of Plaintiff's claims. In seeking summary judgment, NPC relied on Dr. Galleshaw's testimony that she would have prescribed the same course of treatment using Aredia/Zometa even if NPC had warned of the possible connection between bisphosphonates and ONJ.

On December 7, 2010, the MDL Court granted summary judgment in NPC's favor on Plaintiff's claim of negligence per se and denied NPC's motion on Plaintiff's products liability and negligent failure to warn claims. (MSJ Order dated Dec. 7, 2010, [39-5] at 5-7). The MDL Court concluded there was an issue of fact whether NPC's alleged failure to warn of the risk of ONJ caused Plaintiff's injuries, notwithstanding Dr. Galleshaw's testimony that a different or further warning about the risk of ONJ would not have caused her to prescribe a different treatment regimen. (Id. at 4). The MDL Court noted that after NPC disclosed the reported risk of ONJ, Dr. Galleshaw created a handout for patients warning of the risk, told patients they should avoid invasive dental procedures, and discussed with her patients both the handout and the patient's dental health. (Id.). The MDL Court concluded that even if Dr. Galleshaw would have followed the same treatment recommendations, she would have made the recommendation in a different manner, thus "giving Ms. Eberhart a more informed choice concerning the risks." (Id. at 5). According to the MDL Court, this was sufficient to demonstrate a genuine issue of material fact as to causation. (Id.).

On December 27, 2010, the MDL Court remanded this case back to this Court for trial.

On May 27, 2011, NPC renewed its Motion for Summary Judgment, based on a new sworn declaration by Dr. Coggins. In the new declaration, Dr. Coggins expresses his professional opinion that endodontic treatment was not viable for Plaintiff's teeth numbers 18, 19, and 20. NPC argues that because Dr. Galleshaw would not have treated Plaintiff differently if NPC had warned of the risk of ONJ, and because Dr. Coggins would not have performed endodontic treatment at that time because endodontic treatment was not viable, the presence or absence of any warnings by NPC did not cause Plaintiff's injuries because even if warned about ONJ, the undisputed evidence is that she still would have been provided with Aredia/Zometa treatments, she still would have had her teeth extracted, and she still would have developed ONJ. That is, NPC argues that Plaintiff's claim—that had she been warned, she would have sought endodontic treatment rather than extractions and thus the failure to warn caused her injuries—does not have a basis in fact where the only facts in the record are that endodontic treatment was not an option.

Plaintiff responds that Dr. Coggins's declaration is an expert opinion that is not admissible because NPC failed to designate Dr. Coggins as an expert witness, as required by Federal Rule of Civil Procedure 26(a)(2). Without Dr. Coggins's testimony, there is no new evidence and no justification for granting or even

considering NPC's renewed summary judgment motion. Plaintiff further argues that she could have avoided some of her tooth extractions by undergoing endodontic treatment, and would have done so if she had been warned. For support she relies on evidence that Drs. Kirkland and Kakos suggested to her that she return to Dr. Coggins for another endodontic consultation before the extractions of teeth 19 and 20, with the hope that Dr. Coggins might find endodontic treatment to be warranted. The only endodontic evidence available in the record is that endodontic treatment was not an option for Plaintiff.

II. DISCUSSION

A. Legal Standard

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Parties "asserting that a fact cannot be or is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1).

The party seeking summary judgment bears the burden of demonstrating the absence of a genuine dispute as to any material fact. Herzog v. Castle Rock Entm't, 193 F.3d 1241, 1246 (11th Cir. 1999). Once the moving party has met this burden, the non-movant must demonstrate that summary judgment is inappropriate by designating specific facts showing a genuine issue for trial. Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999). Non-moving parties "need not present evidence in a form necessary for admission at trial; however, [they] may not merely rest on [their] pleadings." Id.

The Court must view all evidence in the light most favorable to the party opposing the motion and must draw all inferences in favor of the non-movant, but only "*to the extent supportable by the record*." Garczynski v. Bradshaw, 573 F.3d 1158, 1165 (11th Cir. 2009) (quoting Scott v. Harris, 550 U.S. 372, 381 n.8 (2007)). "[C]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury . . . ." Graham, 193 F.3d at 1282. "If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Herzog, 193 F.3d at 1246. But, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," summary judgment for the moving party is proper. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

B. Motion To Strike The Declaration Of Dr. Coggins

Plaintiff moves to strike the declaration of Dr. Coggins on the grounds that it is inadmissible expert testimony.[7] Federal Rule of Civil Procedure 26(a)(2)(A) provides that "a party must disclose to the other parties the identity of any witness it may use at trial to present [expert] evidence." If the expert witness is not retained by the party to provide expert testimony and is not an employee of the party whose duties regularly involve giving expert testimony, the party must disclose "the subject matter on which the witness is expected to present [expert] evidence," and "a summary of the facts and opinions to which the witness is expected to testify." Fed. R. Civ. Proc. 26(a)(2)(B), (C). NPC's expert disclosures were due April 12, 2010. NPC did not identify Dr. Coggins as an expert. (MDL Court Order dated Feb. 9, 2010, Pl.'s Mot. to Strike Ex. 2; see NPC's Designation of Non-Retained Experts, Pl.'s Mot. to Strike Ex. 4 (Apr. 12, 2010)).

[7] Plaintiff also argues that the declaration is inadmissible because it was obtained through inadmissible ex parte communication between NPC and Dr. Coggins. (Br. Supp. Pl.'s Mot. to Strike [52-1] 6 (quoting Baker v. Wellstar Health Sys., Inc., 703 S.E.2d 601, 605 (2010))). Plaintiff asserts that NPC's communication with Dr. Coggins was improper because NPC failed to notify Plaintiff that NPC planned to interview Dr. Coggins. (Id.). NPC has submitted evidence, however, showing that on April 8, 2011, it informed Plaintiff's counsel of its intent to communicate ex parte with Dr. Coggins. (E-mail from Anthony L. Cochran dated Apr. 8, 2011, 1:20 PM, Def.'s Resp. to Pl.'s Mot. to Strike, Ex. 2). There is no indication that Plaintiff objected to the communication. The Court therefore declines to strike Dr. Coggins's declaration on this ground.

NPC contends that Dr. Coggins "is a treating physician whose testimony is based on personal knowledge acquired from treating Plaintiff," and that Dr. Coggins is a fact witness. (Def.'s Resp. Mot. to Strike 3-4). NPC argues that Rule 26(a)(2) does not require a party to disclose a physician fact witness and because Dr. Coggins offers fact testimony or lay opinion testimony it is admissible at trial and thus can be considered on this motion for summary judgment.

The admissibility of Dr. Coggins's Declaration depends on whether his testimony that in his professional opinion endodontic treatment was not a viable treatment option is the admissible testimony of a treating physician or expert testimony. If the testimony is expert testimony under Federal Rule of Evidence 702, NPC was required to disclose Dr. Coggins as a testifying expert pursuant to the MDL Court's Order.

1. Lay Opinion Testimony Versus Expert Testimony

Federal Rules of Evidence 701 and 702 govern the admissibility of lay opinion testimony and expert testimony. Rule 701 permits non-expert witnesses to testify in the form of opinions that are "(a) rationally based on the perception of the witness, and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Rule 702, in turn, allows "a

witness qualified as an expert by knowledge, skill, experience, training, or education" to testify in the form of an opinion based on "scientific, technical, or other specialized knowledge," so long as certain reliability requirements are satisfied.

The restriction in Rule 701 that lay opinion testimony may not be based on "scientific, technical, or other specialized knowledge within the scope of Rule 702" was added by the 2000 Amendments to the Federal Rules of Evidence. The Advisory Committee explained that the purpose of the change was "to eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing." Fed. R. Evid. 701, Advisory Committee's note to 2000 amendments. "By channeling testimony that is actually expert testimony to Rule 702, the amendment also ensures that a party will not evade the expert witness disclosure requirements set forth in Fed. R. Civ. P. 26 and Fed. R. Crim. P. 16 by simply calling an expert witness in the guise of a layperson." Id. The Committee explained that "the distinction between lay and expert witness testimony is that lay testimony results from a process of reasoning familiar in everyday life, while expert testimony results from a process of reasoning which can be mastered only by specialists in the field." Id. (internal quotation marks omitted).

The Eleventh Circuit has observed that the testimony of treating physicians presents special difficulties. Williams v. Mast Biosurgery USA, Inc., 644 F.3d 1312, 1316 (11th Cir. 2011). "Much of the testimony proffered by treating physicians is an account of their experience in the course of providing care to their patients. Often, however, their proffered testimony can go beyond that sphere and purport to provide explanations of scientific and technical information not grounded in their own observations and technical experience." Id. at 1316-17. As the quoted language from Williams makes clear, a physician who is not qualified as an expert may not "provide explanations of scientific and technical information," unless it is "grounded in [the physician's] own observations and technical experience." Id.; but see Fed. R. Evid. 701 (lay opinion testimony may not be based on "technical" knowledge).

For example, the court in United States v. Henderson, 409 F.3d 1293, 1300 (11th Cir. 2005), approved of a non-expert treating physician testifying about her diagnosis of an individual's injury, in that case a fractured jaw, because it was based on her personal observation during her treatment of that individual and was a necessary component of providing appropriate medical care. Henderson disapproved, however, of allowing the physician to offer her opinion that the fractured jaw was caused by a blow to the left side of the face, because

determining the cause of the injury was not necessary to provide medical treatment in that case and because the opinion on cause was only a hypothesis, which is quintessential expert testimony. Id.

In Williams, the plaintiff wanted to introduce opinion testimony by her treating physicians that a harmful foreign substance they had removed from the plaintiff's abdominal cavity was surgical wrap manufactured by the defendant in that case. 644 F.3d at 1318. The plaintiff argued that the physicians' conclusions that the substance was the defendant's surgical wrap were necessary to treat her and thus admissible under Henderson's approach. The Williams court disagreed, noting that the plaintiff's "treating physicians were concerned with the presence of foreign material and with its effect on her physical condition. The exact identity of the substance was not critical to the decision to remove it." Id. Because "conclusive findings about [the foreign substance's] identity were not necessary to [the plaintiff's] treatment," the opinions of the treating physicians about the identity of the substance were not admissible as lay testimony. Id.

Both Henderson and Williams cite approvingly to the Tenth Circuit's pre-2000 amendment decision in Davoll v. Webb, 194 F.3d 1116 (10th Cir. 1999), which held that a "treating physician, even when testifying as a lay witness, may state 'expert' facts to the jury in order to explain his testimony," id. at 1138 (citing

4 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 701.08 (Joseph M. McLaughlin ed., 2d ed. 1999)). The Davoll court concluded that a treating physician's testimony that explained the meaning of specialized medical terms such as "rehabilitation," "modality," and "soft tissue injury" was not opinion testimony, but the statement of "expert facts," which were admissible to clarify the physician's testimony about his treatment of the plaintiff in that case. Id. The Davoll court also stated that treating physicians who are lay witnesses may offer opinions that are based on their experience as a physician and helpful to understanding their decision making process. Id.

Thus, in the Eleventh Circuit, treating physicians who are not designated as experts may offer "lay" testimony that implicates their specialized experience as a physician if the testimony is an account of their observations during the course of treatment or if it is offered for the purpose of explaining the physician's decision-making process or the treatment provided. See United States v. Henderson, 409 F.3d 1293, 1300 (11th Cir. 2005) (citing Davoll v. Webb, 194 F.3d 1116, 1138 (10th Cir. 1999); Weese v. Schukman, 98 F.3d 542, 550 (10th Cir. 1996)).

The extent to which non-expert treating physicians may offer opinion testimony, however, is strictly and narrowly limited to the above circumstances. Even when offering an opinion based on personal observations, a physician is

using "technical[] or other specialized knowledge" and "a process of reasoning which can be mastered only by specialists in the field," rather than "a process of reasoning familiar in everyday life." Fed. R. Evid. 701 & Advisory Committee's note to 2000 amendments. To allow a non-expert physician to offer opinion testimony beyond those limited circumstances specifically authorized by the Eleventh Circuit risks violating the plain language of Rule 701's prohibition on lay opinion testimony based on scientific, technical, or other specialized knowledge, and would contradict the plain intention of the 2000 amendment to Federal Rule of Evidence 701, as expressed by the Advisory Committee, to subject such testimony to the reliability requirements of Federal Rule of Evidence 702 and the disclosure requirements of Federal Rule of Civil Procedure 26.

2. Application To Dr. Coggins's Declaration

Based on the above principles, the declaration of Dr. Coggins is admissible. He testifies only that he examined Plaintiff on July 8, 2002, and that he would not have performed endodontic treatment on teeth 18, 19, and 20 because endodontic treatment was not a viable treatment option for those teeth. As a "lay" witness, Dr. Coggins may testify about his examination of Plaintiff on July 8, 2002, and he may also testify about his own knowledge about what treatments he was or was not willing to provide at that time. Dr. Coggins's belief about this matter has probative

value because he was the endodontist to whom Drs. Kirkland and Kakos sought to refer Plaintiff for additional endodontic consultation. NPC may use this testimony for the purpose of explaining Dr. Coggins's treatment of Plaintiff on July 8, 2002, his decision to refer Plaintiff to Drs. Kirkland and French, and whether endodontic treatment was an option for Plaintiff based on his evaluation of teeth 18, 19, and 20. That is the extent of his testimony in his April 27, 2011, declaration and it may be considered on NPC's renewed motion for summary judgment.

In conclusion, Plaintiff's Motion to Strike the Declaration of Dr. Coggins is denied. The Declaration may be considered on this motion. Specifically, Dr. Coggins's determination of the viability of endodontic treatment is admissible under Federal Rule of Evidence 701 for the limited purpose of explaining Dr. Coggins's testimony that endodontic treatment of Plaintiff's teeth numbers 18, 19, and 20 was not a viable option based on the condition of these teeth as evaluated by Dr. Coggins on July 8, 2002.[8]

C. NPC's Request For Summary Judgment On Causation Element

Whether proceeding under a strict liability or negligence theory, a plaintiff in a products liability action premised on a failure to warn is required under

[8] The Court notes that Plaintiff did not request an opportunity to conduct any further discovery in this matter after Dr. Coggins's April 27, 2011, declaration was submitted.

Georgia law to show that the absent or defective warning proximately caused the plaintiff's injury. See Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 815 (11th Cir. 2010) (citing Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)). NPC moves for summary judgment on the issue whether its failure to warn of the alleged link between Aredia/Zometa and ONJ proximately caused Plaintiff's injuries.

The MDL Court's order on NPC's first motion for summary judgment narrowed the issues in this case. At issue is not whether Plaintiff would or would not have taken Aredia/Zometa to combat her bone metastases and hypercalcemia, since her treating physician testified that she would have prescribed the treatment regardless of the warning, that Aredia and Zometa were and are the standard of care for Plaintiff's condition, and that Aredia and Zometa very likely are responsible for Plaintiff being alive. Prescription drug manufacturers have a duty in Georgia to warn prescribing physicians, not patients, of the dangers involved with the product, because the physician serves as a learned intermediary between the manufacturer and patient. Id. If a plaintiff's treating physician would have taken the same course of action even with a proper warning from the drug manufacturer, then the causal link is broken and the plaintiff is unable to recover. See id. (citing Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 n.8 (11th Cir. 2002)).

Rather, Plaintiff now contends in this case that had she been warned of the connection between Zometa and ONJ she would have refused the extractions of teeth 19 and 20[9] because she would have sought endodontic treatment based on Drs. Kirkland and Kakos's urging that she get a further endodontic evaluation from Dr. Coggins. NPC contends, based on the declaration of Dr. Coggins, that endodontic treatment was not an option, and there is no evidence by a treating endodontist or dentist that it was. NPC's submits that if it was not possible to avoid extracting the teeth, then even if it had warned Dr. Galleshaw and Dr. Galleshaw had warned Plaintiff, Plaintiff would have undergone the exact same tooth extractions and suffered the exact same injuries, because the only endodontist who has offered any evidence in this case and the dentist to whom Drs. Kirkland and Kakos would have referred Plaintiff for endodontic evaluation, has stated that endodontic treatment was not available for teeth 18, 19, or 20. Since the undisputed evidence is that endodontic treatment was not an option, there is no causal link between NPC's alleged failure to warn and Plaintiff's injuries.

Plaintiff's theory of causation requires her to present some evidence that if she had been warned about the risk of ONJ she would not have undergone the tooth extractions that caused her ONJ. Plaintiff cannot make this showing with

[9] There is no dispute that tooth 18 had to be extracted because of periodontal disease.

respect to tooth 18 because the parties do not dispute that tooth 18 was required to be extracted and thus this extraction could not have caused her ONJ. (See, e.g., Pl.'s Resp. Mot. Summ. J. 14-15; RDSMF ¶¶ 30, 33). Plaintiff's causation theory is that the extraction of tooth 19 is what caused Plaintiff's ONJ because "[Plaintiff's] ONJ originated in the area of tooth 19." (Id. ¶ 33). She argues specifically that her ONJ was caused by the tooth extraction at the site where her ONJ originated, which is the site of tooth 19 rather than 18 or 20. (See, e.g., Kakos Dep. 65:9-11).[10] She also offers evidence that a month before the extraction of tooth 20, Dr. Kakos performed a biopsy in the area of teeth 18 and 19 that tested positive for fragments of dead bone. (Kakos Dep. 85:19-23).

The necessary link in Plaintiff's causal theory therefore is whether tooth 19 could have been saved. If not, it is immaterial Plaintiff was not warned because even if she had been, her stated claim is that she would have avoided the extraction by opting for endodontic treatment If there is no evidence endodontic treatment was an option, there is no causal link between the failure to warn and Plaintiff's injury. On the undisputed record here, endodontic treatment was not available.

[10] Dr. Kirkland also testified that she did not believe Plaintiff's symptoms were related to the extraction of tooth 20 because Plaintiff's symptoms occurred at the extraction site of tooth 19 rather than 20. (Kirkland Dep. 72:24-73:11).

In his Declaration, Dr. Coggins stated that as of July 8, 2002, he determined he would not have performed endodontic treatment on Plaintiff's teeth numbers 18, 19, and 20. Plaintiff is therefore required to present some evidence that would allow a reasonable jury to conclude that if Plaintiff had undergone a second consultation with Dr. Coggins in mid-August 2002, he would have provided endodontic treatment with some chance of saving Plaintiff's tooth number 19.

The entirety of the evidence that Plaintiff presents to create an issue of fact on this crucial link in her theory of causation is the following exchange from Dr. Kirkland's deposition testimony:

> A. . . . Number 19 she was in pain with. I tried to get her to go back and see Dr. Coggins, but she did not want a root canal or to even talk with Dr. Coggins about it, so she wanted 19 removed.
> Q. Now, did you discuss with her specifically the possibility of trying to retain Tooth No. 19?
> A. Yes.
> Q. And do you recall why she did not want to do so?
> A. She did not—declined. She just declined the endodontic consultation . . . .

(Kirkland Dep. 36:16-37-1). In other words, the only evidence presented by Plaintiff that tooth 19 could have been saved is that Dr. Kirkland, a periodontist, suggested that Plaintiff go back to Dr. Coggins for another endodontic consultation.

The evidence presented by Plaintiff is not sufficient to demonstrate a genuine issue of disputed fact whether tooth 19 could have been saved. Dr. Kirkland's testimony only supports that she urged Plaintiff to return to Dr. Coggins for another endodontic consultation. The Court has reviewed Dr. Kirkland's testimony in its entirety. Dr. Kirkland expressly agreed with Dr. Coggins's initial assessment that Plaintiff's dental problems were periodontal in nature and not endodontic (Kirkland Dep. 31:25-32:6), which specifically disputes that endodontic treatment even was an option. Although, soon before the extraction of tooth 19, Dr. Kirkland suggested to Plaintiff that she have Dr. Coggins take a second look at her teeth, Dr. Kirkland also clearly deferred to Dr. Coggins on the issue of endodontic treatment. The record shows that Dr. Kirkland never testified that tooth 19 could have been saved and she did not even estimate the viability or likelihood of success of endodontic treatment.[11] Nothing in Dr. Kirkland's testimony suggests she had any opinion that Dr. Coggins would change his diagnosis about whether Plaintiff's dental problems were endodontic. More importantly, there is nothing in Dr. Kirkland's testimony that would support any reasonable inference about Dr. Kirkland's belief about the likelihood or unlikelihood of saving tooth 19. The evidence that Plaintiff has presented simply

[11] Nor did Plaintiff's counsel lay a foundation for Dr. Kirkland to give an expert opinion about the appropriateness of endodontic treatment.

is not meaningfully probative of whether tooth number 19 could have been saved. In contrast, Dr. Coggins has submitted a current statement reiterating his view that as far back as July 2002 he concluded that Plaintiff's problems were not endodontic in nature. There simply is no support for Plaintiff's present litigating position that an endodontic solution was an alternative for her if she had been told there was an ONJ risk if tooth 19 was extracted. The facts rather support that the extraction of tooth 19 was necessary because of her severe periodontal disease of that tooth.

Once NPC demonstrated the absence of a genuine disputed fact on the issue of causation, Plaintiff was required to demonstrate that summary judgment is not appropriate by designating specific facts raising a genuine issue for trial. Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999). This lawsuit has been pending for nearly four years and Plaintiff has advocated her current theory of causation for at least over a year. Plaintiff has had ample opportunity to conduct discovery and obtain some evidence probative of whether endodontic treatment was a viable option that could have saved tooth 19. Instead, Plaintiff has relied entirely upon one treating periodontist's statement that she thought a second endodontic consultation was suggested. This single statement is not sufficient to create a genuine issue of material fact whether tooth 19 was required to be

extracted. Because Plaintiff's ONJ is claimed to have originated at the site where tooth 19 was extracted, Plaintiff has failed to demonstrate an issue of fact whether NPC's purported failure to warn proximately caused Plaintiff's alleged ONJ.

The Court concludes on the record here that Plaintiff has not shown that NPC's failure to warn was a cause of her alleged injury and has not shown that there is an issue of fact on causation. Based on the evidence in the record as presented by the parties, the Court concludes that there are no facts to support that endodontic treatment was available to avoid the extraction of tooth 18 or of tooth 19, which was the site of Plaintiff's claimed ONJ. Accordingly, the Court finds there is no disputed fact regarding causation and the motion for summary judgment is required to be granted.

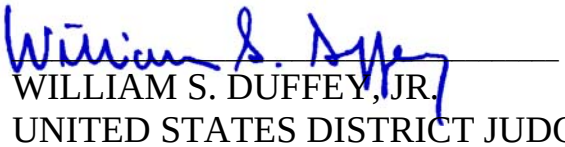
III. CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED that Plaintiff Susan Eberhart's Motion to Strike Declaration of Dr. Randall A. Coggins, DMD, MS [52] is **DENIED**.

IT IS FURTHER ORDERED that Novartis Pharmaceuticals Corporation's Renewed Motion for Summary Judgment [39] is **GRANTED**.

SO ORDERED this 31st day of October, 2011.



WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE