IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DEBORAH GARRISON,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 2:11-CV-589-WKW
	)	[WO]
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Before the court are Defendant Novartis Pharmaceuticals Corporation's motion for summary judgment (Docs. # 45, 46) and its motion to exclude certain testimony of Dr. Vishtasb Broumand (Doc. # 47). Each motion has been fully briefed, and the motion for summary judgment has been supplemented with additional authorities. (*See* Docs. # 51, 53, 63, 67, 69 (motion for summary judgment); 60, 61 (motion to exclude Dr. Broumand).) Upon consideration of the parties' arguments, the evidence, and the relevant law, the court finds that the motions are due to be granted.

I. JURISDICTION AND VENUE

The court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a). The parties do not contest personal jurisdiction or venue.

II. BACKGROUND

A. Facts

1. *Aredia® and Zometa®*

Ms. Garrison has suffered osteonecrosis, or bone death, of the jaw ("ONJ") which has rendered her permanently disfigured and caused enduring pain. She alleges two drugs, Aredia® and Zometa®, which were marketed, distributed, promoted, tested, labeled, and sold by Novartis, caused her injuries. Zometa® is the successor drug of Aredia®, and both are reported to increase the risk of developing ONJ. Both drugs are nitrogenous bisphosphonates that are prescribed by doctors for the management of metastatic disease to the bone and other degenerative bone conditions. Bisphosphonates are useful for the prevention of the loss of bone mass because they inhibit osteoclasts, the bone cells that re-absorb and destroy old bone tissue.

However, bisphosphonates can have devastating effects on the jaw. The jaw bone is unique in that it is subject to heightened stress, and thus, it "remodels" – *i.e*., replaces old bone with new bone – at a faster than normal rate as compared to other bones. Bisphosphonates like Aredia® and Zometa® have an alleged "site preference" for high remodeling areas and thus impact those areas more markedly. The drugs can cause changes to both the lower and upper jaw bones (the mandible and maxilla, respectively). Patients who have been exposed to bisphosphonates

can develop ONJ many years after receiving bisphosphonate therapy because the drugs have a long half-life in the bone. The same patients also have a particularly heightened risk for developing ONJ following oral surgery.

In her complaint, Ms. Garrison alleges that Novartis knew or should have known that bisphosphonate drugs could cause ONJ. She claims that as early as 1996, Novartis knew that ONJ had been reported in clinical trials and that by 2002, Novartis had learned from doctors and oral surgeons that some patients who had received bisphosphonate treatments were suffering with severe ONJ symptoms. Novartis did not begin to place warnings about ONJ on its drugs until September 2004, and it did not notify dental professionals of ONJ risks until May 2005. She claims that Novartis has continued to downplay the known risks of taking Aredia® and Zometa®, has rebranded the drugs' names to conceal the negative connection to ONJ, and has misreported safety data to the Food and Drug Administration.

2. *Ms. Garrison's Medical History*

In 1998, a metastatic bone survey revealed osteopenic lesions and degenerative bone changes in Ms. Garrison's cervical spine. These changes in her spine required two different surgeries in 1999. Ms. Garrison received care from David Morrison, M.D., and later, Khalid Matin, M.D., both oncologists at Montgomery's Cancer Center. By September 2001, Dr. Morrison formally

diagnosed Ms. Garrison with Stage 1a Dune-Salmon multiple myeloma, a bone cancer that causes bone lesions, bone pain, and bone deterioration.

Under Dr. Morrison's care, Ms. Garrison received intravenous infusions of Aredia® from September 2001 until April 2002. At that time, Novartis offered no warnings of ONJ, and it is undisputed that Dr. Morrison did not convey the risk of ONJ to Ms. Garrison when he first prescribed bisphosphonate therapy. Dr. Morrison stopped the bisphosphonate therapy for a period of time because Ms. Garrison's cancer was in remission and the drug was not ameliorating her bone pain.[1]

In September 2005, Ms. Garrison began taking intravenous Zometa® treatments. By that time, Novartis had updated its warnings and had notified doctors of the reported risk of ONJ.[2] Dr. Morrison claims that he communicated the risk of ONJ to Ms. Garrison in September 2005, (*see* Morrison Dec., at ¶¶ 5–6 (Doc. # 46-1)), but Ms. Garrison denies that she was warned.

In 2009, Ms. Garrison experienced pain in her left jaw and a fever, and her symptoms worsened even though she took a lengthy course of antibiotics. Ms.

[1] This fact, as alleged by Ms. Garrison, does not comport with Novartis's representation that "Dr. Morrison continued Ms. Garrison on monthly generic pamidronate [the equivalent of Aredia®] therapy *from 2001 through August 2005*." (Doc. # 46, at 4 (emphasis added).) Whether bisphosphonate therapy ceased from 2002 to 2005 is immaterial to the outcome of this case.

[2] Dr. Morrison received a "Dear Doctor" letter from Novartis in September 2004 about the reported association between ONJ and bisphosphonates.

Garrison reports that she maintained regular dental hygiene and that her jaw pain was not caused by a lack of dental care. The jaw pain caused her to have difficulty eating and sleeping. In January 2009, Dr. Matin, who by that point had become Ms. Garrison's treating oncologist, discontinued the Zometa® treatments because Ms. Garrison was considering oral surgery and Dr. Matin wanted to reduce the heightened risk of developing ONJ.

In April 2009, Ms. Garrison consulted Dr. David Roden, an oral maxillofacial surgeon at the University of Alabama at Birmingham ("UAB") Oral Surgery Clinic. Dr. Roden observed purulent discharge (*i.e.*, pus) and recommended extraction of fractured tooth # 20 on Ms. Garrison's left mandible. Purulent discharge is indicative of osteomyelitis, an inflammation of the bone caused by a bacterial infection. At that time, Dr. Roden did not observe any exposed necrotic bone, and Ms. Garrison's x-rays did not indicate ONJ. Ms. Garrison waited about a year before having tooth # 20 extracted by another dentist in Montgomery.

In July 2010, Ms. Garrison returned to UAB and saw Dr. Victor Szymela who discovered exposed necrotic bone in the left mandible at the extraction site. A CT scan taken on June 28, 2010, revealed "erosion of the left body of the mandible with periosteal new bone formation, suggesting chronic inflammation that is seen in ONJ." (Broumand Rep., at 4 (Doc. # 60-5, at 5).) Ms. Garrison has continued

to have exposed necrotic bone and to endure pain in her jaw, which has been observed and treated by Dr. Szymela, Dr. Somsak Sittitavornwong, and Dr. Lisa Miller. Under their care, Ms. Garrison's jaw has failed to respond to multiple debridements, intravenous and/or oral antibiotics, and other conservative therapies.[3] Dr. Miller, a board certified oral and maxillofacial surgeon, performed a biopsy of Ms. Garrison's jaw bone in January 2011, which revealed necrotic bone consistent with osteonecrosis. At that time, Dr. Miller diagnosed Ms. Garrison with bisphosphonate-related ONJ.[4]

B. Procedural History

Ms. Garrison filed this suit in July 2011. Her complaint alleges strict liability (Count I), negligent manufacture (Count II), negligent failure to warn (Count III), and breach of implied warranty (Count V),[5] and seeks compensatory and punitive damages and attorneys' fees and costs. The case remained stagnant for about fourteen months while the parties anticipated transfer by the Judicial Panel on Multidistrict Litigation to the Middle District of Tennessee. Once it later

[3] A debridement is the removal of dead or damaged bone or tissue down to a "bleeding bone" to improve the healing potential of remaining healthy bone or tissue.

[4] In addition to the injuries alleged in her complaint, Ms. Garrison has continued to endure pain, difficulty eating, joint and nerve problems, visits to the emergency room, and long-term antibiotic therapy during the course of this litigation.

[5] Novartis has argued that Ms. Garrison lacks evidence that Novartis ever made any promise or warranty to her. (Doc. # 46, at 21.) Ms. Garrison has conceded her claim for breach of express warranty (Count IV). (*See* Doc. # 53.) Thus, summary judgment is due to be granted in favor of Novartis on the breach of express warranty claim.

became clear that the JPML would not transfer the action, a scheduling order was entered. (*See* Doc. # 35.) Novartis's pending *Daubert* and summary judgment motions have been timely submitted.

Ms. Garrison has retained various experts to support her claims, including Dr. Vishtasb Broumand, an assistant professor at the University of Miami School of Medicine who specializes in oral and maxillofacial surgery. He opines that Ms. Garrison's ONJ was caused by her long-term exposure to bisphosphonate treatment. Novartis moves to exclude portions of Dr. Broumand's testimony pursuant to *Daubert* because Dr. Broumand's report contains admitted errors and because Dr. Broumand's differential diagnosis[6] fails to adequately consider and eliminate another cause for the onset of osteonecrosis, namely osteomyelitis. (*See* Doc. # 47.) The motion to exclude Dr. Broumand's testimony is entwined with one of Novartis's arguments in support of summary judgment. (*See* Doc. # 46, at 19–21.)

[6] A differential diagnosis is a process whereby an expert determines all the possible causes of a malady like ONJ and then attempts to eliminate causes until reaching a cause that cannot be eliminated or determining which cause of several causes is the most likely cause among the others. Differential diagnosis is also called "differential etiology." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1194 n.5 (11th Cir. 2010).

III. STANDARDS OF REVIEW

A. *Daubert* Motion

Federal Rule of Evidence 702 provides that

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court explained that it is the district court's function to serve as "gatekeeper" and to ensure that an expert's testimony rests on a reliable foundation and is relevant. When assessing the reliability of scientific testimony, the court should consider the four factors laid out in *Daubert*. *Id.* at 593–94.[7]

"The trial court's gatekeeping function requires more than simply taking the expert's word for it." Fed. R. Evid. 702, advisory committee's notes, 2000

[7] The factors are: "(1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the theory or technique used by the expert has been subjected to peer review and publication; (3) whether there is a known or potential error rate of the methodology; and (4) whether the technique has been generally accepted in the relevant scientific community." *United Fire & Cas. Co. v. Whirlpool Corp.*, 704 F.3d 1338, 1341 (11th Cir. 2013).

amendments) (internal citations and quotations omitted); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). The burden is on the proponent of the expert to show by a preponderance of the evidence that the expert is qualified to testify, that "the methodology by which the expert reaches his conclusions is sufficiently reliable," and that the expert's scientific or technical testimony will assist the trier of fact in understanding the evidence and deciding the facts. *Hendrix*, 609 F.3d at 1194.

B. Summary Judgment Motion

To succeed on summary judgment, the movant must demonstrate "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). The court must view the evidence and the inferences from that evidence in the light most favorable to the nonmovant. *Jean-Baptiste v. Gutierrez*, 627 F.3d 816, 820 (11th Cir. 2010).

The party moving for summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This responsibility includes identifying the portions of the record illustrating the absence of a genuine dispute of material fact. *Id*. Or a movant who does not have a trial burden of production

can assert, without citing the record, that the nonmoving party "cannot produce admissible evidence to support" a material fact. Fed. R. Civ. P. 56(c)(1)(B); *see also* Fed. R. Civ. P. 56 advisory committee's note ("Subdivision (c)(1)(B) recognizes that a party need not always point to specific record materials. . . . [A] party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact."). If the movant meets its burden, the burden shifts to the nonmoving party to establish – with evidence beyond the pleadings – that a genuine dispute material to each of its claims for relief exists. *Celotex*, 477 U.S. at 324. A genuine dispute of material fact exists when the nonmoving party produces evidence allowing a reasonable fact finder to return a verdict in its favor. *Waddell v. Valley Forge Dental Assocs.*, 276 F.3d 1275, 1279 (11th Cir. 2001).

IV. DISCUSSION

A. Defining the Legal Standard for Ms. Garrison's Remaining Claims

Novartis argues that all of Ms. Garrison's claims are governed by the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") and Alabama's "'failure to warn' negligence law." (Doc. # 46, at 12, 12 n.48.)[8] To succeed on a claim under the AEMLD, the plaintiff must prove

[8] More specifically, Novartis asserts that AEMLD encompasses Ms. Garrison's strict liability (Count I), breach of implied warranty (Count V), and defective manufacture claims (Count II). (Doc. # 46, at n.48.) Novartis's argument is supported by Alabama case law, and

> (1) that an injury was caused by one who sold a product in a defective condition that made the product unreasonably dangerous to the ultimate user or consumer; (2) that the seller was engaged in the business of selling such a product; and (3) that the product was expected to, and did, reach the user without substantial change in the condition in which it was sold.

Tillman v. R.J. Reynolds Tobacco Co., 871 So. 2d 28, 31 (Ala. 2003) (alterations, quotation marks, and citation omitted).[9]

In AEMLD cases involving unsafe prescription drugs, "the adequacy of the [manufacturer's] accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984). Alabama courts follow the learned-intermediary doctrine, and thus, a "manufacturer's duty to warn" a consumer about a drug "is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1274 (5th Cir. 1974)). "The principle behind the learned-intermediary doctrine is that . . . the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits

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Ms. Garrison does not dispute this characterization of her claims. (*See* Doc. # 53, at 7 (describing her claim as a "failure to warn negligence action").)

[9] The plaintiff makes a prima facie case of liability under the AEMLD even though the defendant exercised all possible care in preparation and sale of the product. *Cassrell v. Altec Indus., Inc.*, 335 So. 2d 128, 132–33 (Ala. 1976). The AEMLD has been described as "a hybrid or strict liability and traditional negligence concepts." *Lowe v. Metabolife Int'l, Inc.*, 206 F. Supp. 2d 1195, 1199 (S.D. Ala. 2002) (citing *Pitts v. Dow Chem. Co.*, 859 F. Supp. 543, 550 (M.D. Ala. 1994)). Common law defenses – *e.g.*, contributory negligence, assumption of the risk, and, sometimes, lack of causal relation – remain available to AEMLD defendants. *Id.*

of a particular course of treatment for the patient." *Wyeth, Inc. v. Weeks*, ___ So. 3d. ___, 1101397, 2013 WL 135753, at *18 (Ala. Jan. 11, 2013), *reargument granted* (June 13, 2013).

However, "if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Id.* at *19. "The patient must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Id.*; *see also Campbell v. Robert Bosch Power Tool Corp.*, 795 F. Supp. 1093, 1097 (M.D. Ala. 1992) (delineating the elements of a typical negligence claim including duty, breach of duty, proximate cause, and injury). Hence, the plaintiff must show not only that an inadequate warning was given, but also that an adequate warning would have prevented her injury. *See Deere & Co. v. Grose*, 586 So. 2d 196, 198 (Ala. 1991) (citing *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 970–71 (Ala. 1985)).

B. Arguments Raised by Novartis in Support of Summary Judgment

Novartis advances four arguments in support of its motion for summary judgment on Ms. Garrison's AEMLD and negligent failure to warn claims.

1. *Whether Novartis's Warnings Were Adequate*

Novartis added a warning about ONJ to Aredia® and Zometa® labels in September 2003.[10] Novartis contends that Ms. Garrison lacks evidence that Novartis knew or should have known of the risk of ONJ prior to that date. Novartis says that the issue is identical to the one presented in *D'Agnese v. Novartis Pharmaceuticals Corporation*, 952 F. Supp. 2d 880, 891–92 (D. Ariz. 2013), where the court concluded that the plaintiff lacked evidence that Novartis had information about ONJ risks when the plaintiff first began receiving Aredia® treatments.[11] Novartis argues that Ms. Garrison's "warnings" experts, Doctors Robert Marx and James Vogel, do not disagree that Novartis had no duty to warn about ONJ prior to September 2003 because there was no scientific or medical

[10] Novartis advised the FDA that it was revising the "Adverse Reactions" portion of the labels for Aredia and Zometa to include the following:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa® or other bisphosphonates, to concomitant drugs or other therapies (*e.g.* chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (*e.g.* anemia, infection, pre-existing oral disease).

D'Agnese v. Novartis Pharms. Corp., 952 F. Supp. 2d 880, 887 (D. Ariz. 2013).

[11] The plaintiff in *D'Agnese* received Aredia treatments from December 1998 to May 2002, and Zometa treatments from June 2002 to October 2005. The court reasoned at summary judgment that, although the plaintiff argued that Novartis's early testing and clinical trials were insufficient, he did not support his contention with evidence. 952 F. Supp. 2d at 892.

knowledge to support the link between bisphosphonates and ONJ. (*See* Docs. # 46-15, 46-16.)[12]

Ms. Garrison responds that other courts have found that plaintiffs have produced sufficient evidence that Novartis "intentionally concealed the risk of ONJ and attempted to subvert medical inquiry regarding the risks of ONJ." (Doc. # 53, at 8 (quoting *Fussman v. Novartis Pharm. Corp.*, No. 1:06CV149, 2011 WL 5836928, at *5 (M.D.N.C. Nov. 21, 2011) (opinion and order denying post-trial motions for judgment as a matter of law), *aff'd*, 509 F. App'x 215 (4th Cir. 2013)). Ms. Garrison cites evidence that Novartis knew of ONJ cases during its clinical trials going back to 1991. She further claims that an oral surgeon at New York City's Long Island Jewish Medical Center, Dr. Sal Ruggerio, reached out to Novartis in April 2002 about whether bisphosphonates could cause ONJ. At a meeting at NYU in December 2002, Dr. Ruggerio reported the incidence of roughly twenty cases of ONJ in cancer patients who had received bisphosphonate treatments. A Novartis representative in the audience heard Dr. Ruggerio's concerns and reported the information to the company, who began a response campaign of sorts in 2003, not to inform doctors, but to discourage oncologists from believing reports in the medical community that bisphosphonates were responsible for ONJ. On the basis of this evidence, Ms. Garrison contends that the

[12] In those exhibits, each expert acknowledges that prior to 2003, there was no reason for Novartis to know of ONJ risks related to bisphosphonate treatments.

adequacy of Novartis's early warnings is a question for trial. (*See* Docs. # 53-4, 53-5, 53-6, 53-7.)

Novartis replies that Ms. Garrison's own experts admit that Novartis's warnings were adequate both before and after the ONJ warning was added in 2003. It is true that Ms. Garrison does not dispute that Novartis's warnings from September 2003 forward were adequate. As Novartis has emphasized, Drs. Marx and Vogel think that the warnings in that time frame were as good as they could have possibly been at the time. But Novartis's reply does not rebut Ms. Garrison's assertion that her evidence may be sufficient to convince a jury that Novartis could have warned about ONJ prior to September 2003.

Viewing the evidence in the light most favorable to Ms. Garrison, the court finds that the adequacy of Novartis's warnings prior to 2003 is genuinely disputed, and therefore, summary judgment is due to be denied on this ground.

2. *Whether Ms. Garrison Assumed the Risk of Developing ONJ*

Novartis claims that, after Dr. Morrison disclosed the risk to Ms. Garrison in 2005, she appreciated the risk of ONJ and voluntarily exposed herself to it by consenting to continued Zometa® infusions. Novartis argues that Ms. Garrison further assumed the risk by having tooth # 20 extracted in spite of being warned by Dr. Roden that oral surgery would put her at greater risk for developing ONJ. A defendant asserting assumption of the risk must show that the plaintiff knew about

the risk, appreciated the risk, and voluntarily exposed herself to it. *Ex parte Barran*, 730 So. 2d 203, 206 (Ala. 1998).

Ms. Garrison responds that her testimony contradicts Dr. Morrison's statement that he disclosed the risks of taking Zometa® to her when he recommended that she switch from Aredia® to Zometa® in September 2005. She also argues that Dr. Morrison's testimony is self-serving and his credibility is damaged by the revocation of his medical license in Alabama and in other states. As for the argument that she assumed the risk of ONJ by choosing oral surgery, Ms. Garrison responds that a jury could view her surgery as a medical necessity for which she had no meaningful choice.

The assumption of the risk defense is ordinarily a question for a jury, *Ex parte Barran*, 730 So. 2d at 206, and this case is no exception. Whether Ms. Garrison knew about the risk of taking Zometa® and whether she voluntarily exposed herself to the risk of oral surgery are genuinely disputed. Summary judgment is due to be denied on the ground that Ms. Garrison assumed the risk of developing ONJ.

3. *Whether a Different Warning Would Have Prevented Ms. Garrison's ONJ*

Novartis asserts that Ms. Garrison cannot show that a different warning would have stopped Dr. Morrison from prescribing bisphosphonates or that it

would have prevented Dr. Roden from recommending extraction of Ms. Garrison's tooth. Dr. Morrison has stated that he still would have prescribed Aredia® and Zometa® because the benefit (*i.e.*, the prevention of bone deterioration, especially in Ms. Garrison's already vulnerable spine) outweighed the risk that she might develop ONJ. (Morrison Dec., at ¶ 7 (Doc. # 46-1) ("If I knew in September 2001 what I learned in 2004 about the risk of ONJ, I still would have prescribed Aredia® to Ms. Garrison.").) Moreover, according to Novartis, Dr. Roden's records confirm that there was no alternative to his recommendation to extract tooth # 20, notwithstanding Ms. Garrison's heightened risk of developing osteonecrosis after exposure to bisphosphonates. Thus, Novartis contends that its inadequate warning was not the proximate cause of Ms. Garrison's injuries, and she therefore cannot prevail on her claims. Novartis cites numerous similar cases where district courts have dismissed the plaintiffs' claims at summary judgment because of lack of proximate causation.[13]

[13] *See, e.g.*, *D'Agnese*, 952 F. Supp. 2d at 891 ("When a prescriber is aware of the risks associated with a prescription medication and chooses to prescribe the medication in spite of these risks, or would not have modified the decision even if alternate warnings had been provided, the plaintiff has failed to establish the manufacturer's failure to warn as the proximate cause of the plaintiff's alleged injury."); *Payne v. Novartis*, 967 F. Supp. 2d 1223, 1233 (E.D. Tenn. 2013) (granting summary judgment to Novartis where treating physician testified that he "would have prescribed [Aredia and Zometa] to [the plaintiff] regardless of Novartis's [ONJ] warning"); *Ingram v. Novartis*, 888 F. Supp. 2d 1241, 1245–46 (W.D. Okla. 2012) (granting summary judgment where treating oncologist testified that, if he had known that Aredia was associated with a risk of ONJ, he would have prescribed it for the plaintiff anyway); *Luttrell v. Novartis*, 894 F. Supp. 2d 1324, 1344–46 (E.D. Wash. 2012) (finding that the plaintiff failed to "sustain his burden to prove proximate cause because he c[ould] not prove that stronger warnings would have affected [the doctor's] decision to prescribe Aredia and Zometa"); *Zimmerman v.*

A defendant's tortious conduct must be the proximate cause of an injury. *See Vines v. Plantation Motor Lodge*, 336 So. 2d 1338, 1339 (Ala. 1976); *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 518 (11th Cir. 2007) (requiring the plaintiff to prove proximate causation on both his AEMLD and negligent failure to warn claims). That is, the "injury must be a natural and probable consequence of the [defendant's] negligent act or omission which an ordinarily prudent person ought reasonably to foresee would result in injury." *Vines*, 336 So. 2d at 1339. But "[w]here some independent agency intervenes and is the immediate cause of the injury, the party guilty of prior negligence is not liable." *Hall v. Booth*, 423 So. 2d 184, 185 (Ala. 1982). "Generally the question of proximate cause is for the jury, but when facts are such that reasonable men must draw the same conclusion, the question of proximate cause is one of law for the courts." *Peevy v. Ala. Power Co.*, 393 So. 2d 971, 973 (Ala. 1981).

Ms. Garrison responds that the court cannot grant summary judgment in reliance upon Dr. Morrison's self-serving declaration testimony. Ms. Garrison

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Novartis, 287 F.R.D. 357, 361–62 (D. Md. 2012) (granting summary judgment to Novartis based on testimony of treating dentist and periodontist that extracted tooth could not be salvaged notwithstanding contrary testimony from the plaintiff's expert); *Eberhart v. Novartis*, 867 F. Supp. 2d 1241, 1255 (N.D. Ga. 2011) (granting summary judgment to Novartis where the plaintiff's evidence was insufficient to demonstrate that her tooth could have been saved and oral surgery avoided).

In each case, the district courts applied the law of the states in which they sit. There is no indication that Alabama's law of proximate causation differs or will require a different result in this case.

believes that the revocation of Dr. Morris's medical licence requires a jury to assess his credibility.[14] She further argues that the medical necessity of her tooth extraction is of no import and proposes that, if she had been adequately warned in 2001 of the risk of ONJ, she may have elected to not receive the bisphosphonate treatments at all or for as long as she did, thereby eliminating or substantially reducing her heightened risk of developing of ONJ following her tooth extraction.

Ms. Garrison's rebuttal argument stands on the following premises. First, Novartis could have provided an adequate warning about ONJ prior to 2003, and specifically, at or before the time that Dr. Morrison first prescribed Aredia® infusions in 2001. Second, if Novartis had been able to provide an adequate warning of ONJ in 2001 and had actually provided it, then Ms. Garrison would have been duly warned by Dr. Morrison. And third, if she had been so warned, she might have chosen to decline bisphosphonate treatments, thereby eliminating her heightened risk of ONJ. Ms. Garrison cannot progress from the second to third step of her hypothesis, however, because of the learned-intermediary doctrine and the testimony of Dr. Morrison. Dr. Morrison testifies that even with a more adequate warning prior to 2003 or 2004, he still would have prescribed bisphosphonate infusions because the benefit (the prevention of substantial bone

[14] Even though Dr. Morrison's testimony is self-serving, there appears to be no dispute that the prescription and administration of intravenous bisphosphonates for bone cancer patients was and is standard procedure among oncologists, which lends credibility to Dr. Morrison's testimony that he would not have adjusted or withheld bisphosphonate therapy.

loss) outweighed the risk of ONJ. Dr. Morrison's disregard of the risk of ONJ disrupts Ms. Garrison's theory that Novartis's inadequate warnings were the proximate cause of her injuries.

Ms. Garrison asserts that Dr. Morrison's testimony must be weighed by a jury and that it cannot be credited at this stage of the litigation. (*See* Doc. # 53, at 10 (citing *Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1070 (S.D. Ill. 2007); *Golod v. La Roche*, 964 F. Supp. 841, 857 (S.D.N.Y. 1997); *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993)).) Each of the cited cases supports the proposition that only "self-disserving" testimony is adequate to support a defendant's motion for summary judgment. Hence, these courts have said that unless a doctor's testimony is wholly self-disserving, a jury should be allowed to assess the credibility of his testimony. Although it is acknowledged that Dr. Morrison's testimony is not conclusively self-disserving, as that term is defined by some courts, there is no similar pronouncement from the Eleventh Circuit of which this court is aware.

Instead, Eleventh Circuit authority supports Novartis's position that it does not matter that Dr. Morrison has a dubious professional record and that a jury might be persuaded to discredit his testimony. The court must ask "whether [Dr. Morrison's] decision to prescribe [Aredia®] to [Ms. Garrison] ultimately hinged on the information (accurate or inaccurate) that he obtained from [Novartis]," and

if not, whether Ms. Garrison has evidence to rebut Dr. Morrison. *Bodie*, 236 F. App'x at 522 n.12. Dr. Morrison's testimony is unambiguous that an earlier warning would not have affected his decision to prescribe bisphosphonates, and Ms. Garrison has not refuted his testimony to create a genuine dispute of material fact. *See D'Agnese*, 952 F. Supp. 2d at 891 (finding that the plaintiffs failed to offer evidence that Novartis's better and earlier warnings would have altered the treating oncologist's decision to prescribe Aredia®); *Bodie*, 236 F. App'x at 522 n.12 (requiring the plaintiff to refute testimony, not just undermine its credibility).

Additionally, Ms. Garrison's contention that her tooth extraction was medically necessary proves rather than defeats Novartis's argument that proximate cause is lacking. (*See* Doc. # 63, at 4–5.) That is to say, Ms. Garrison's unavoidable need for oral surgery was an intervening cause of the onset of ONJ, and an adequate warning would not have prevented the need to extract her tooth. *Cf. Eberhart*, 867 F. Supp. 2d at 1254–56 (concluding that the plaintiff failed to raise a genuine issue of fact for trial when she failed to furnish evidence to support her theory that a tooth could have been saved and an extraction avoided).

For these reasons, Novartis has met its burden of showing as undisputed fact that its allegedly inadequate warnings for Aredia® and Zometa® were not the proximate cause of Ms. Garrison's ONJ. Accordingly, Novartis's motion for

summary judgment is due to be granted on her negligent failure to warn and AEMLD claims.

However, there is an additional, meritorious argument in favor of Novartis's summary judgment motion

4. *Whether Ms. Garrison Lacks Admissible Expert Testimony that Aredia® and Zometa® Caused Her ONJ*

Novartis also contends that Ms. Garrison has no expert testimony that passes *Daubert*'s standard by which she can prove that Aredia® and Zometa® as opposed to osteomyelitis caused the onset of her ONJ. (Doc. # 46, at 19–21; *see also* Doc. # 47 (Mot. to Exclude Certain Test. of Dr. Broumand).) Novartis emphasizes that necrotic bone did not appear until 2010, months after Ms. Garrison's tooth was extracted, which suggests that the pus-producing osteomyelitis that necessitated the extraction of tooth # 20 was the specific cause of her ONJ. In cases of bisphosphonate-related ONJ, necrotic bone typically precedes infection, which was not the case in Ms. Garrison's presentation to Dr. Roden. According to Novartis, Ms. Garrison's specific-causation expert Dr. Broumand concedes that osteomyelitis could have caused of Ms. Garrison's ONJ. (*See* Dec. 16, 2013 Broumand Dep., at 63–64 (Doc. # 46-2, at 19–20); Nov. 15, 2013 Broumand Dep., at 65–66 (Doc. # 46-10, at 12–13).) Dr. Broumand also conceded at his deposition that when Ms. Garrison presented to Dr. Roden in April 2009, Dr. Roden ordered

x-rays, and the x-rays did not indicate any necrotic bone in Ms. Garrison's jaw. (*See* Dec. 16, 2013 Broumand Dep., at 64–65, 68–69 (Doc. # 46-2, at 20–21, 22–23).) Because of these admissions, Novartis contends that Dr. Broumand failed to adequately analyze and eliminate osteomyelitis through the process of differential diagnosis.[15]

In support of its position, Novartis cites *Harvey v. Novartis Pharmaceuticals Corp.*, 895 F. Supp. 2d 1206, 1212–13 (N.D. Ala. 2012), where the court refused to admit an expert's opinion because of the plaintiff's failure to show that the expert performed a proper differential diagnosis. The *Harvey* court followed the Eleventh Circuit's directive in *Guinn v. AstraZeneca Pharmaceuticals LP*, 602 F.3d 1245, 1253 (11th Cir. 2010), that an expert "must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Guinn* requires that an expert "provide a reasonable explanation as to why he . . . has concluded that any alternative cause suggested by the defense was not the sole cause of the plaintiff's injury." *Id.* (internal quotation marks and citation omitted). It is not enough for the expert to simply assert that he performed differential diagnosis in reaching his opinion; he must take "serious account of other potential causes." *Id.* (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999)).

[15] Novartis also criticizes Dr. Broumand's report for its erroneous references to dates and to certain teeth that required extraction. (Doc. # 47, at 1–3.) While errors within the report are perhaps a sign that the report was prepared hurriedly, they are not necessarily cause to reject Dr. Broumand's ultimate conclusions.

Ms. Garrison responds briefly in her summary judgment opposition that a triable issue of fact remains because it is not clear that she had osteomyelitis as opposed to secondary infections resulting from already-present osteonecrosis. (*See* Doc. # 53, at 14 (citing Broumand Report at 8).) In his report, Dr. Broumand opines that Ms. Garrison "continued to have exposed bone with no infectious etiology whatsoever" so he "*know*[*s*] *with certainty* that that the diagnosis of osteomyelitis could not have been correct." (Broumand Rep., at 6 (Doc. # 53-1, at 7) (emphasis added).) Instead, Dr. Broumand believes that Ms. Garrison's jaw became "secondarily infect[ed]" as a result of the onset of bisphosphonate-related ONJ. (Broumand Report at 6 (Doc. # 53-1, at 7).) Ms. Garrison responds further in her opposition to Novartis's motion to exclude portions of Dr. Broumand's testimony, (*see* Doc. # 60), that any disagreement over Dr. Broumand's differential diagnosis should go to the weight of his expert opinion testimony rather than to its admissibility. *See In re Fosamax Prods. Liab. Litig*., 688 F. Supp. 2d 259, 267–68 (S.D.N.Y. 2010) ("Only serious flaws in reasoning will warrant exclusion. As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process – competing expert testimony and active cross-examination." (internal quotation marks omitted)). Ms. Garrison defends Dr. Broumand's report as adequate because it explains how he reaches his conclusion that bisphosphonates caused Ms. Garrison's ONJ, and she emphasizes

that Dr. Broumand does not have to eliminate all possible causes in order to conduct a reliable and admissible differential diagnosis. *See Guinn*, 602 F.3d at 1253.

In reply, Novartis stresses Dr. Broumand's contrary deposition testimony, given after the submission of his report, where he agreed that Dr. Roden observed Ms. Garrison's fractured and infected tooth in April 2009, over a year prior to Dr. Szymela's observation of exposed necrotic bone at the extraction site in July 2010. (Doc. # 61, at 5 (citing Dec. 16, 2013 Broumand Dep. at 64–65).) Novartis further emphasizes that the pre-extraction x-rays of Ms. Garrison's mouth from April 2009 showed no indication of ONJ in her left mandible. It therefore concludes that Dr. Broumand's deposition testimony cannot support his report's differential diagnosis conclusion that Ms. Garrison's ONJ was caused by bisphosphonates rather than osteomyelitis.

Rule 702 and *Daubert* require that an expert's methodology be sufficiently reliable. A differential diagnosis is a reliable way to reach an opinion on causation, so long as the method is applied reliably to the facts of a case. Dr. Broumand's report fails to show that he conducted a sufficiently thorough analysis to support his conclusive elimination of osteomyelitis as a specific cause of ONJ. While Dr. Broumand's report purports to eliminate osteomyelitis as the likely cause of Ms. Garrison's ONJ, he glosses over the fact that Dr. Roden observed

only purulent discharge and no exposed necrotic bone in April 2009. The report also neglects to mention the absence of any evidence of osteonecrosis in the April 2009 x-rays. Moreover, Dr. Broumand's report specifically indicates his belief that osteomyelitis was not the cause of Ms. Garrison's ONJ because her condition was unresponsive to IV antibiotics and debridements. (*See* Broumand Rep., at 6 (Doc. # 60-5, at 7).) Yet Dr. Broumand admitted at his deposition that Ms. Garrison's medical records actually did not show that she received these treatments prior to the extraction of tooth # 20 when her symptoms indicated osteomyelitis. (*See* Dec. 16, 2013 Broumand Dep. at 80–82 (Doc. # 47-2, at 14–16).) These factors compromise the reliability of Dr. Broumand's firm conclusion that Ms. Garrison's ONJ was solely caused by her exposure to bisphosphonates, and Ms. Garrison fails to meet her burden of showing that it is more likely than not that Dr. Broumand's differential diagnosis analysis is scientifically sound. *See Hendrix*, 609 F.3d at 1194; *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005) ("The *Daubert* 'requirement that the expert testify to scientific knowledge – conclusions supported by good grounds for each step in the analysis – means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible.'") (quoting *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002)).

For these reasons, Novartis's motion to exclude portions of Dr. Broumand's testimony is due to be granted. Consequently, Novartis's corresponding motion for summary judgment is due to be granted because Ms. Garrison lacks admissible expert testimony to show specific causation.

V. CONCLUSION

In accordance with the foregoing findings, it is ORDERED that Novartis's motion for summary judgment (Doc. # 45) and motion to exclude certain testimony of Dr. Broumand (Doc. # 47) are GRANTED. All other pending motions are DENIED as moot.

A separate final judgment will be entered.

DONE this 2nd day of July, 2014.

/s/ W. Keith Watkins
CHIEF UNITED STATES DISTRICT JUDGE