IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:11-CV-680-D

JIMMY EARP and PATRICIA EARP,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**ORDER**
	)	
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
	)	
	)	
Defendant.	)	

On September 1, 2006, Jimmy Earp ("Earp") and Patricia Earp (collectively, "plaintiffs") and others filed a complaint alleging various claims against Novartis Pharmaceuticals Corporation ("Novartis" or "defendant") arising from osteonecrosis of the jaw ("ONJ") allegedly caused by use of Aredia and Zometa, two prescription bisphosphonate medications that Novartis produced and sold. Earp v. Novartis Pharm. Corp., No. 5:06-CV-350-D, [D.E. 1] (E.D.N.C. Sept. 1, 2006). The action was transferred to the United States District Court for the Middle District of Tennessee for Multi-District Litigation ("MDL") proceedings. See id., [D.E. 11–12] (E.D.N.C. Nov. 6, 2006); In re Aredia & Zometa Prods. Liab. Litig., No. 3:06-md-1760 (M.D. Tenn.). After discovery proceedings and severance of the Earps' case, the MDL court transferred the case back to this court for further proceedings, including (if needed) a trial [D.E. 44]. On November 19, 2012, the court entered a scheduling order for pretrial motions [D.E. 60].

On November 8, 2012, plaintiffs moved to amend the complaint and filed a supporting memorandum and exhibit [D.E. 55–56]. On December 3, 2012, Novartis responded in opposition [D.E. 64]. On December 20, 2012, Novartis moved to exclude certain expert testimony as either

irrelevant or unreliable pursuant to Daubert v. Merrel Dow Pharm., Inc., 509 U.S. 579 (1993). See [D.E. 66, 68, 70, 72, 74, 76]. On January 22, 2013, plaintiffs responded in opposition to the motions to exclude expert testimony [D.E. 80, 82–83] and filed a cross motion seeking to collaterally estop defendant's motions to exclude [D.E. 84]. Novartis replied on February 4, 2013 [D.E. 85–90] and responded to plantiffs' estoppel request on February 15, 2013 [D.E. 93]. On December 20, 2012, Novartis moved for summary judgment [D.E. 78] and filed a supporting memorandum and exhibits [D.E. 79]. Plaintiffs responded in opposition [D.E. 81], and Novartis replied [D.E. 91]. As explained below, the court denies plaintiffs' motion to amend, denies defendant's Daubert motions, and grants in part and denies in part defendant's motion for summary judgment.

I.

As for plaintiffs' motion to amend the complaint, plaintiffs filed the motion on November 8, 2012, approximately 21 months after the close of fact discovery and 18 months after the deadline for filing dispositive motions. See Scheduling Order [D.E. 27] 4. The scheduling order did not set a deadline for filing amended pleadings. See id.

The court should freely give leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). However, when a party seeks to amend a complaint after the date set forth in a scheduling order for such motions, the party must establish good cause under Rule 16. See Nourison Rug Corp. v. Parvizian, 535 F.3d 295, 298–99 (4th Cir. 2008); see Fed. R. Civ. P. 16(b)(4). Although the scheduling order did not set a deadline for filing amended pleadings, the deadline for filing dispositive motions necessarily implied a deadline for amended pleadings. After all, any new pleadings would require the court to amend the scheduling order to allow Novartis to file responsive dispositive motions and to conduct any necessary discovery. Thus, plaintiffs must meet the good cause standard of Rule 16.

Plaintiffs seek to add a claim under North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA"), N.C. Gen. Stat. § 75-1. Plaintiffs offer no explanation for the late addition of the claim one and a half years after the deadline for dispositive motions even though the proposed new claim allegedly is "based completely on previously plead[ed] and discovered facts." Pls.' Mem. Supp. Mot. Amend [D.E. 56] 2.

Plaintiffs have failed to show good cause under Rule 16. See Nourison Rug Corp., 535 F.3d at 298–99. Moreover, adding the UDTPA claim would prejudice Novartis and further delay the case. Thus, even if the court applied only Rule 15, the court would still deny the motion due to prejudice. See id. at 298 (describing Rule 15 standard). Accordingly, the court denies the motion to amend.

II.

Novartis has filed a number of motions seeking to exclude the testimony of plaintiffs' experts under Daubert and Federal Rule of Evidence 702. Specifically, Novartis filed motions to exclude (1) testimony of Dr. Robert Marx regarding causation, Novartis's state of mind, Novartis's operation of clinical trials, and the efficacy of certain dental treatments [D.E. 66]; (2) testimony of plaintiffs' regulatory expert Dr. Suzanne Parisian [D.E. 68]; (3) testimony of Dr. Keith Skubitz about ONJ, the drafting and approval of Aredia and Zometa labels, FDA dosing information, and the efficacy of preventative dentistry for patients using Aredia and Zometa [D.E. 70]; (4) testimony of Dr. James Vogel [D.E. 72]; (5) testimony regarding specific causation of plaintiff Earp's ONJ by retained expert Dr. Frederick Nance and plaintiff Earp's treating physicians Dr. George Blakey, Dr. Mark Yoffe, Dr. Alan Kritz, Dr. Daniel Petrocella, and Dr. Steven Davis [D.E. 74]; and (6) general causation testimony of Dr. Wayne Ray [D.E. 76].

Rule 702 provides:

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.

Fed. R. Evid. 702. Daubert clarifies that Rule 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. The court recognizes that "Rule 702 was intended to liberalize the introduction of relevant expert evidence," but that "expert witnesses have the potential to be both powerful and quite misleading." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (quotation omitted).

The proponent of the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. Id. A district court has broad latitude in determining whether to admit proposed expert testimony. United States v. Gastiaburo, 16 F.3d 582, 589 (4th Cir. 1994).

Courts have distilled Rule 702's requirements in two crucial inquiries: whether the proposed expert testimony is relevant and whether it is reliable. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999); Daubert, 509 U.S. at 589; United States v. Forrest, 429 F.3d 73, 80 (4th Cir. 2005). To be relevant, the proposed expert testimony must be helpful to the trier of fact. See Daubert, 509 U.S. at 591–92. "Testimony from an expert is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." Kopf v. Skyrm, 993 F.2d 374, 377 (4th Cir. 1993); accord Koger v. Norfolk S. Ry. Co., No. 1:08-0909, 2010 WL 692842, at *1 (S.D. W. Va. Feb. 23, 2010) (unpublished).

"[T]he test of reliability is flexible and the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability

determination." United States v. Wilson, 484 F.3d 267, 274 (4th Cir. 2007) (quotation omitted); see Kumho Tire, 526 U.S. at 141–42. A witness may qualify to render expert opinions in any one of the five ways listed in Rule 702: knowledge, skill, experience, training, or education. See Kumho Tire, 526 U.S. at 147. When a party challenges an expert's qualifications, "'the test for exclusion is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered.'" Kopf, 993 F.2d at 377 (quoting Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799 (4th Cir. 1989)). "In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999). In analyzing reliability, a court should consider factors such as:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper, 259 F.3d at 199; see Daubert, 509 U.S. at 592–94.

Much of the parties' dispute regarding expert testimony concerns whether each of the various experts is qualified and has a reliable basis to offer testimony as to the alleged causal connection between Aredia and Zometa and ONJ. The court analyzes the arguments seriatim.

As for Dr. Marx, Dr. Marx is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of certain treatments in preventing bisphosphonate-induced ONJ ("BIONJ"), general causation based on adverse event reports, and the biological mechanism by which bisphosphonates may cause BIONJ. To the extent plaintiffs seek to introduce Dr. Marx's opinion

on whether Novartis acted in "bad faith," the court agrees with Novartis that Dr. Marx lacks a basis to testify on the subject, and such testimony will be excluded. Likewise, the court will not permit Dr. Marx to criticize Novartis's clinical trials or opine on patients in those trials given his lack of expertise or any reliable methodology.

As for Dr. Parisian, Dr. Parisian is an expert whose testimony may be helpful to a jury regarding the FDA drug-approval process including regulations governing the approval, advertising, and marketing of pharmaceuticals. To the extent she also seeks to opine on whether Novartis complied with the regulations, industry ghostwriting or funding of scientific studies, causation, whether the labels provided adequate warnings in this case, state of mind, or to provide other testimony that would unduly prejudicial, irrelevant, or outside the scope of her expertise, the court will not allow her to do so.

As for Dr. Skubitz, Dr. Skubitz is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of pretreatment dental screening in preventing BIONJ. The court, however, will not permit him to testify about alternative dosing or labeling.

As for Dr. Vogel, Dr. Vogel is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of pretreatment dental screening in preventing BIONJ, the incidence rate of ONJ, the efficacy of reduced dosing schedules, and general causation. The court, however, will not permit him to testify about corporate conduct, labeling, or the biological mechanism by which bisphosphonates may cause BIONJ.

As for Doctors Nance and Blakey, these witnesses are qualified experts and each has a reliable basis to offer testimony regarding specific causation of plaintiff Earp's ONJ. Plaintiffs do not appear to contend that Doctors Yoffe, Kritz, Petrocella, and Davis will testify that Aredia or Zometa specifically caused plaintiff Earp's ONJ, and plaintiffs do not argue that these treating

physicians have any basis for so opining. See Pls.' Mem. Opp. Mot. Exclude [D.E. 80] 24–25. Accordingly, any such testimony will be excluded. However, Doctors Petrocella and Davis are experts qualified to discuss how bisphosphonate-related ONJ causes difficulty in treatment and how their profession's understanding of Aredia and Zometa and its links to ONJ would have affected their treatment of plaintiff Earp.

In accordance with the foregoing conclusions, the court denies in part Novartis's motions to exclude expert testimony [D.E. 66, 68, 70, 72, 74, 76]. The court notes that many of Novartis's objections go to the weight of the experts' testimony and not to its admissibility. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596. The court will further consider as part of the motions in limine or at trial whether the testimony of any expert should be limited as irrelevant, unduly prejudicial, or outside the scope of his or her expertise. The court denies plaintiffs' cross-motion [D.E. 84] regarding the motions to exclude as moot.

III.

Next, the court considers Novartis's motion for summary judgment [D.E. 15, 78]. The court reviews Novartis's motion for summary judgment under the familiar standard of Rule 56. Summary judgment is appropriate when, after reviewing the record taken as a whole, no genuine issue of material fact exists, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986). The party seeking summary judgment bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). Once the moving party has met its burden, the nonmoving party may not rest on the allegations or denials in its pleading, Anderson, 477 U.S. at

248–49, but "must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (emphasis and quotation omitted). A trial court reviewing a motion for summary judgment should determine whether a genuine issue of material fact exists for trial. Anderson, 477 U.S. at 249. In making this determination, the court must view the evidence and the inferences drawn therefrom in the light most favorable to plaintiffs. Scott v. Harris, 550 U.S. 372, 378 (2007).

Novartis argues that (1) plaintiffs' claims are barred by North Carolina's statute of limitations; (2) plaintiffs have presented no admissible evidence of causation; (3) plaintiffs have failed to show that Novartis failed to provide a timely or adequate warning, or that a different warning would have prevented Earp's jaw injury; (4) plaintiffs fail to provide evidence of any express warranty that Novartis violated; (5) plaintiffs have no evidence that Aredia and Zometa were not fit and effective for their intended purpose; (6) plaintiffs' strict liability, negligent manufacturing, and negligent design claims fail as a matter of law; and (7) Patricia Earp's claim for loss of consortium fails because it is derivative of the other claims. Def.'s Mem. Supp. Mot. Summ. J. [D.E. 79] 1–2.

North Carolina's statute of limitations for personal injury provides a three-year limitations period that does not "accrue until bodily harm to the claimant . . . becomes apparent or ought reasonably to have become apparent to the claimant." N.C. Gen. Stat. § 1-52(16). In the case of diseases, the limitations period does not begin until a medical diagnosis reveals the nature of plaintiff's disease. See Wilder v. Amatex Corp., 314 N.C. 550, 559–61, 336 S.E.2d 66, 71–72 (1985); cf. Wilson v. McLeod Oil Co., 327 N.C. 491, 512, 398 S.E.2d 586, 596–97 (1990); Black v. Littlejohn, 312 N.C. 626, 643–45, 325 S.E.2d 469, 480–82 (1985); Crawford v. Boyette, 121 N.C. App. 67, 70–72, 464 S.E.2d 301, 304 (1995). Viewing the evidence in the light most favorable to

plaintiffs, Earp's jaw condition was not diagnosed as bisphosphonate-related ONJ until October 11, 2005. E.g., Blakey Dep. [D.E. 80-14] 113–14. Therefore, viewing the evidence in the light most favorable to plaintiffs, plaintiffs' September 1, 2006 complaint was timely filed.

Next, Novartis argues that plaintiffs lack evidence of causation. Plaintiffs, however, have proffered sufficient, admissible expert testimony concerning causation to create a genuine issue of fact for trial.

As for the adequacy of the warnings concerning Aredia and Zometa, numerous material factual issues remain, such as what Novartis knew about the risks of bisphosphonates, when it knew or should have known those risks, and whether it adequately conveyed the risks to physicians. Furthermore, viewing the evidence in the light most favorable to plaintiffs, plaintiffs have produced evidence that creates a genuine issue as to whether Earp's treatment would have been different if Novartis had provided adequate warning. See, e.g., Yoffe Dep. [D.E. 80-16] 119–20; Davis Dep. [D.E. 80-24] 96; Kritz Dep. [D.E. 80-27] 90–92.

As for plaintiffs' claim for breach of express warranty, "[a] claim for breach of express warranty . . . requires proof of (1) an express warranty as to a fact or promise relating to the goods, (2) which was relied upon by the plaintiff in making his decision to purchase, (3) and that this express warranty was breached by the defendant." Harbor Point Homeowners' Ass'n ex rel. Bd. of Dirs. v. DJF Enters., Inc., 206 N.C. App. 152, 162, 697 S.E.2d 439, 447 (2010). Plaintiffs have not provided evidence of any express warranty Novartis or its agents made or violated. See Pls.' Mem. Opp. Summ. J. [D.E. 81] 27–28. Accordingly, the court grants summary judgment to Novartis on this claim.

As for plaintiffs' claim for breach of implied warranty, Novartis argues that plaintiffs' claim "is actually a failure to warn claim under a different name." Def.'s Mem. Supp. Mot. Summ. J. 22.

However, "a failure to warn of dangerous propensities concerning a product may create an action of breach of implied warranty of merchantability." Bryant v. Adams, 116 N.C. App. 448, 468, 448 S.E.2d 832, 843 (1994); see Nicholson v. Am. Safety Util. Corp., 124 N.C. App. 59, 69, 476 S.E.2d 672, 678 (1996). Viewing the evidence in the light most favorable to plaintiffs, genuine issues of material fact remain concerning this claim. Thus, the court denies summary judgment on this claim.

As for plaintiffs' claims for strict liability and manufacturing defect, plaintiffs "are not pressing" either claim in this case. Pls.' Mem. Opp. Summ. J. 28. Accordingly, the court grants summary judgment to Novartis on these claims.

As for plaintiffs' design defect claim, plaintiffs must prove, among other things, either one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
>
> (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

N.C. Gen. Stat. § 99B-6(a); see DeWitt v. Eveready Battery Co., 144 N.C. App. 143, 154–55, 550 S.E.2d 511, 518–19 (2001), aff'd, 355 N.C. 672, 565 S.E.2d 140 (2002). Plaintiffs have not alleged or produced evidence of any safer alternative design that would have prevented or substantially reduced the risk of harm of using Aredia or Zometa. Furthermore, plaintiffs' evidence shows that physicians continue to prescribe and use Aredia and Zometa after becoming aware of the allegedly defective design of the products. E.g., Yoffe Dep. 118–19. Thus, plaintiffs have not shown that the formulation of these medications was so unreasonable that a reasonable person would not use or consume them. Accordingly, the court grants summary judgment to Novartis on this claim.

Finally, the parties agree that Patricia Earp's loss of consortium claim rises or falls with plaintiffs' other claims. Accordingly, the court denies summary judgment on this claim.

IV.

In sum, the court DENIES plaintiffs' motion to amend the complaint [D.E. 55], DENIES in part defendant's motions to exclude expert testimony [D.E. 66, 68, 70, 72, 74, 76], DENIES as moot plaintiffs' cross-motion regarding the motion to exclude [D.E. 84], and GRANTS IN PART AND DENIES IN PART defendant's motion for summary judgment [D.E. 78]. The parties shall schedule and complete mediation no later than November 15, 2013.

SO ORDERED. This 11 day of September 2013.

JAMES C. DEVER III
Chief United States District Judge