UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
ALEXANDRIA DIVISION

ARLENE PERKINS	**CIVIL ACTION NO. 12-662**
VERSUS	**JUDGE TRIMBLE**
NOVARTIS PHARMACEUTICALS CORPORATION	**MAGISTRATE JUDGE KIRK**

MEMORANDUM RULING

The above-captioned case was assigned to the docket of the undersigned after transfer from a multidistrict litigation (hereinafter, "MDL") group most recently located in the Middle District of Tennessee. After transfer to this court, defendant Novartis Pharmaceuticals Corporation (hereinafter, "Novartis") filed a case-specific Daubert motion[1] and a motion for summary judgment.[2] After careful review of the law and argument advanced by the parties, the court finds that both motions should be GRANTED and, accordingly, that plaintiff's claims against defendant in this matter should be DENIED and DISMISSED with prejudice.

I. Relevant Facts

Plaintiff, Arlene Perkins, brings this suit against defendant Novartis alleging liability under theories of products liability, negligence and breach of express and implied warranties.[3] Plaintiff was prescribed and administered doses of the intravenous bisphosphonate drug

[1] Novartis' Daubert motion originally challenged the admissibility of five proposed expert witness' testimony in this case: Dr. Marx, Dr. Kim, Dr. Hargis, Dr. Carlton and Dr. Hathorn. Plaintiff has voluntarily withdrawn the proposed testimony of Drs. Hargis, Carlton and Hathorn, leaving only Drs. Marx and Kim for the court's consideration. See, R. 158 at p.1, n.1.
[2] R. 154, 155.
[3] R. 1 (Complaint).

Zometa, manufactured and sold by Novartis.[4] Plaintiff alleges that, as a result of taking Zometa, she developed osteonecrosis of the jaw (hereinafter, "ONJ").[5] Plaintiff further alleges that Zometa contained a defect in its design which created a risk of harm to consumers and that such defect was known or should have been known to Novartis; that Novartis failed to warn physicians and consumers of the risk of harm of which it knew or should have known; that Novartis failed to exercise reasonable care in the design, testing, development, manufacturing, labeling, marketing, distribution and sale of Zometa, thereby causing harm to plaintiff; that Novartis breached the express warranty made to consumers by its authorized agents that Zometa was "safe, effective and fit for its intended use"; and that Novartis breached the implied warranty that Zometa was of "merchantable quality[,]...safe, and fit for its intended use."[6]

Within the context of these allegations, plaintiff proposes to offer the expert witness testimony of Dr. Robert Marx and Dr. David Kim on the issue of medical causation. Novartis objects to the admissibility of these witness' testimony on the basis that neither prospective witness' testimony meets the standards of admissibility under Daubert v. Merrill Dow Pharmaceuticals, Inc.[7] Considering these objections, Novartis also seeks summary judgment in its favor as to all claims by plaintiff in this case on the basis that, without causation evidence, plaintiff is unable to bear her burden of proof and, accordingly, Novartis is entitled to judgment as a matter of law.

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[4] Id. at ¶¶ 6 – 8, 13.
[5] Id. at ¶ 14.
[6] Id. at ¶¶ 16 – 43.
[7] 509 U.S. 579 (1993).

II. Daubert Standard

Expert witness testimony, like all other evidence sought to be introduced at trial, must first be deemed relevant to the issues in the case.[8] The court must, then, decide any preliminary questions regarding whether a proposed expert witness is qualified or is subject to privilege.[9] Fed. R. Evid. 702, regarding expert witness testimony, provides that

> A witness who is qualified as an expert by knowledge, skill, experience, training, or eduction 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.

The court applies Rule 702 to scientific and non-scientific expert testimony and must ensure that any expert testimony admitted is both relevant and reliable.[10] "Although there are no certainties in science, the expert must present conclusions that are grounded in the methods and procedures of science."[11] The role of the district court, when presented with a challenge to proposed expert witness testimony, is that of a "gatekeeper."[12]

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[8] Fed. R. Evid. 401.
[9] Fed. R. Evid. 104(a).
[10] Knight v. Kirby Inland Marine, Inc., 482 F.3d 347 (5th Cir. 2007); Kumho Tire Co., Ltd. V. Carmichael, 526 U.S. 137 (1999); Daubert., 509 U.S. 579 (1993).
[11] Daubert, 509 U.S. at 590; Wells v. SmithKline Beecham Corp., 601 F.3d 375, 378 (5th Cir. 2010).
[12] U.S. v. Fullwood, 342 F.3d 409, 412 (5th Cir. 2003).

III. Brief summary of plaintiff's medical and dental history

On July 30, 1996, plaintiff was diagnosed with breast cancer (D. Ex. 1), and beginning the following day she began chemotherapy with the drugs Cisplastin, VP-16 and CAF (D. Ex 2). On October 18, 1996, she underwent a modified right breast mastectomy, the surgeon noting that the plaintiff suffered from Stage III cancer. In January, 1997, plaintiff was treated with high dose chemotherapy with Cytoxan, Carboplatin, and Thiotepa (D. Ex. 4). She underwent bone marrow transplant at the LSU Medical Center's Hospital in Shreveport, Louisiana after which her treating physician, Dr. Barry Weinberger, prescribed chest wall irradiation and commencement of Tamoxifen. (D. Ex. 5) Plaintiff's oncologist, Dr. Gary Burton, to prevent bone cancer metastasis, prescribed Zometa, which she received every three months, beginning in 2003 and ending on February 9, 2005. (D. Ex. 6 & 7)

Plaintiff's deposition testimony revealed that she had not been seen regularly by a dentist as an adult, and was vague as to how many of her teeth had been extracted prior to March 2005. (D. Ex. 8, pgs. 100-103). Plaintiff's dentist, Dr. Burke, extracted tooth # 30 in March of 2005. According to Mrs. Perkins, that tooth was pulled because she had a toothache (D.Ex. 8 @ p. 154). The Court notes there is some apparent confusion as to which tooth was pulled. Dr. Burke refers to tooth #30. Dr. Hathorn refers to tooth #29 (D. Ex. 10). Dr. Carlton also notes that the extraction was #29 (D. Ex. 12). In his notes, Dr. Carlton remarks that the socket was bare, with exposed "cortical" bone when he saw her on April 25, 2005. When he saw her on April 27, 2005, he noted that she was better and there was no drainage. (Id.)

Plaintiff saw Dr. David Kim, a board certified oral surgeon and Assistant Professor at the LSU Health Sciences Center in Shreveport, on May 13, 2005. (D. Ex. 13, pg. 49.) At that time he did not note that there was any exposed bone in plaintiff's mouth and that plaintiff's complaint may have been related to non-healing of the soft tissue (D. Ex. 13, pg. 49-50). At the Health Sciences Center, on May 26, 2005, plaintiff underwent a procedure described as debridement of bone and extraction of tooth #28. The surgery was performed by Dr. Kevin J. Connor (D. Ex. 19), who was identified by Dr. Kim as a first year resident in oral surgery (D. Ex. 13 @ pg. 38, 75-77.) The last formal medical record furnished to the court is exhibit 15, which is a follow-up visit at the Health Sciences Center in Shreveport on June 3, 2005, 8 days postoperative. The clinic notes said at that time Mrs. Perkins had a good healing response from the surgery. Although the medical records furnished to the court end with the June 3, 2005, note, there was a telephone conference between the court and counsel for plaintiff and defendant on May 15, 2013. The court was advised at that time that, thankfully, there had been no bone metastasis experienced by Mrs. Perkins and, about 17 years following the mastectomy, she has been testing as cancer free. With respect to her dental problem related to the surgery at the lower jaw extraction site, it is the court's recollection that one of the attorneys (believed to be defense counsel) advised that Mrs. Perkins' recovery has been uneventful following about two weeks of antibiotics postoperatively. Regardless of which attorney so informed the court, opposing counsel did not take issue with the statement. The court does note that plaintiff had all of her remaining teeth removed in August of 2005, not because of any issue of osteonecrosis of the jaw, but simply because of periodontal disease and decay (D. Ex. 13, p 114, dep. of Dr. Kim).

IV. Dr. Robert Marx

Dr. Marx is an eminent oral surgeon who is a Professor of Surgery and Chief of the Division of Oral and Maxillofacial Surgery at the University of Miami Miller School of Medicine. His curriculum vitae is most impressive and reveals much in depth research into various fields of oral surgery with much emphasis on bisphosphonate-induced osteonecrosis of the jaw (BIONJ). He makes a very compelling case that bisphosphonates in numerous cases throughout the land have caused and are causing OMJ. Without question, he is qualified to testify in this general field. It is not necessary for the purposes of this case that the court make any determination of the accuracy of Dr. Marx's opinion. The court has heard nothing in the way of countervailing evidence from defendant, and should such evidence exist, it may be as much or more persuasive.

The focus of the court's attention as it pertains to this motion will be on the discrete issue of whether or not Dr. Marx should be permitted to testify in this case for this particular plaintiff, Mrs. Arlene Perkins. Dr. Marx has prepared an expert report addressing the general question of BIONJ which consists of 19 pages and is identified as Exhibit G to the declaration of Mr. Daniel Osborn regarding the opposition to defendant's Daubert motion. He also has submitted an expert report specific to the case of Mrs. Perkins (D. Ex. 18). In preparation for the latter, Dr. Marx identified the evidence he considered in forming his opinion and preparing his report as the medical and dental healthcare records from Dr. Archie Breazeale, M.D.; Dr. David Carlton, Oral and Maxillofacial Surgeon; Dr. David Kim, Oral and Maxillofacial Surgeon; Dr. Paul Hargis, DDS, and Dr. Thomas Hawthorn, DDS. The only other evidence that he considered was the deposition of Dr. David Kim dated March 12, 2008. He apparently did not study or

review the deposition of the plaintiff, Arlene Perkins. (Dr. Marx's report, pg. 4) Following his review, Dr. Marx found as a fact that as a result of Zometa injections and complications therefrom, Mrs. Perkins required "several surgeries" as well as numerous clinic treatment visits. He opined "to a reasonable degree of medical probability and certainty" that Mrs. Perkins suffered from bisphosphonate-induced osteonecrosis of the jaw linked specifically to Zometa. (Id, p.5)

Dr. Marx states that other experts consider risk factors for developing OMJ to include cancer, radiation therapies, chemotherapy, corticosteroid therapy, immunotherapy, periodontal disease, dental extractions, intra-oral trauma, diabetes, hypertension, anemia, smoking, alcohol abuse and obesity. Dr. Marx concludes as follows:

"For the following reasons, I have ruled these conditions and treatments out as the cause of Mrs. Perkins's BIONJ: (i) based on my experience with BIONJ; (ii) because there is no credible scientific evidence that these treatments or conditions cause osteonecrosis of the jaw, and/or (iii) there is no evidence that she received these treatments or have these conditions." Dr. Marx's first assessed basis for his opinion is classic ipse dixit and will be totally disregarded by the court. The second basis stated is a possible valid reason, although the court was provided with much purportedly credible scientific evidence to the contrary with defendant's Daubert motion and supporting memorandum. The third basis stressed by Dr. Marx leads the court to wonder whether Dr. Marx in fact reviewed the records that he professed. In the discussion of Mrs. Perkins's past medical and dental history, the court, making clear references to portions of the medical records, noted that Mrs. Perkins had cancer, had radiation therapy, had chemotherapy in high doses because she was considered a high risk patient, had

periodontal disease which caused her to request removal of her remaining teeth, had dental extractions, and smoked despite her doctors' advice that she quit. (D. Ex. 8, pg. 131) Dr. Marx is grossly in error in his third reason, and that in itself should be considered a fatal flaw in the basis for his "opinion."

Dr. Marx, in reaching his "opinion", grossly overstates the treatment Mrs. Perkins required at Dr. Kim's clinic. He states that she required several surgeries and numerous clinical treatments because of Zometa. That is simply not supported by the record. There was one surgery at the LSU Health Sciences Center for debridement of bone and extraction of a tooth connected with the non-healing of the tooth extraction in March of 2005. That procedure was performed on May 26, 2005 and involved removal of necrotic bone surrounding the extraction socket down to fresh bleeding bone. A visit to Dr. Kim's clinic eight days later showed good healing response. Based upon the information from the attorneys during the conference of May 15, 2013, there have been no other surgeries and no treatment specifically directed to the problem at issue in this case except completing the course of antibiotics that followed the surgery. When confronted with direct testimony from Dr. Kim that he found no evidence of non-healing extraction sockets or anything related to exposed bone in the area of the affected extraction, Dr. Marx, without satisfactory explanation, simply opines that Dr. Kim was "terribly confused." (Dr. Marx dep. p. 184) When Dr. Marx refers to several surgeries and "complications" from Zometa he is apparently unwilling to accept the direct and unequivocal testimony of Dr. Kim, the treating oral surgeon, that the teeth extractions in August 2005 had absolutely nothing to do with BIONJ. Those are the only "surgeries" mentioned in the evidence.

In this regard, Dr. Marx is displaying an obvious lack of objectivity required of an expert witness in quest of the truth in a court of law.

Finally, the court turns to the 19 page expert report of Dr. Marx which provides a general discussion of BIONJ. On page 6 of this report, Dr. Marx states the following:

"Once BIONJ develops, minor surgeries are counterproductive and result in further exposed bone. Therefore, these individuals must live with exposed bone, taking antibiotics and antiseptic mouthwashes to control infections. In my experience, in approximately 10% of cases, these measures prove to be ineffective and removal of a large portion of the jaw becomes necessary."

Dr. Marx provides his own determinative factors for reaching a diagnosis of BIONJ. The presence of such factors in Mrs. Perkins's case is totally lacking. Dr. Marx does not find a single hallmark of BIONJ to fit his own description. There was a minor surgery performed on May 26, 2005. At that time, there was no exposed bone and had not been on May 13, 2005 when Dr. Kim first saw Mrs. Perkins. This minor debridement procedure was examined 8 days later and found to have a good healing response. There is no evidence that the procedure resulted in "further exposed bone." There is no evidence that Mrs. Perkins is living with exposed bone and is continuing to take antibiotics and utilize antiseptic mouthwashes to control infections. There is no evidence that she has undergone removal of a large portion of the jaw. In summary, Dr. Marx is willing to render a diagnosis of BIONJ in Mrs. Perkins's case without having made one evidentiary-supported factual finding that she has even one indicia of the disease according to his specifications. There may very well be cases in which Dr. Marx has done a more careful study and review of all the evidence regarding the patients in question. Following that, he may

have been able to match the actual symptoms and treatment of the patients to his own standards for diagnosing BIONJ. Be that as it may, he has not done so in this case. He failed to provide the court with any reliable evidence whatsoever to substantiate his bare opinions, and that is not sufficient to satisfy Daubert. Dr. Marx will not be permitted to express an opinion regarding BIONJ in Mrs. Perkins.

V. Dr. David Kim

While neither party disputes the qualifications of Dr. Kim as a competent oral surgeon, there is no evidence whatever that he is possessed of any professional expertise in the particular field of bisphosphonates as they may relate to osteonecrosis of the jaw. The information regarding Dr. Kim from both parties is devoid of any evidence that would qualify Dr. Kim to testify as an expert in that general field. As to Mrs. Perkins specifically, Dr. Kim played a limited role in her treatment at the LSU Health Sciences Center. The operative report of May 26, 2005 of that institution contains a preoperative and postoperative diagnosis, as to Mrs. Perkins, of bisphosphonate necrosis of the lower jaw. This was not Dr. Kim's diagnosis. It was the diagnosis of the first year surgical resident, Dr. Connor, who was directed by Dr. Dreher as the teaching physician. Dr. Kim testified that he was "overseeing the entire thing", and that he was present during the procedure. He further testified that he only reviewed the operative report for the first time in preparation for his deposition, which was taken on March 12, 2008, almost three years after the operation. (Kim dep. pgs. 75-77) At pages 135 and 136 of his deposition, Dr. Kim admits that there was nothing whatsoever in the record citing his own interaction with Mrs. Perkins that would direct a diagnosis of osteonecrosis of the jaw. He had no differential diagnosis, no formal analysis, and upon being asked whether he had any

scientifically reliable evidence that what Mrs. Perkins had in May 2005 was bisphosphonate-induced OMJ, he responded as follows:

"I don't have evidence that she has bisphosphonate-associated osteonecrosis. That was my medical opinion." (Kim dep. pg. 161)

He admits that that opinion was solely based on the fact that Mrs. Perkins had been administered Zometa and that there was some sort of non-healing at the site of the tooth extraction. (Kim dep. pgs. 160-162)

Dr. Kim does not provide the court with any information that would tempt, much less persuade, the court to recognize him as an expert to testify that the plaintiff in this case suffered from osteonecrosis of the jaw in any way related to treatment with Zometa. He will not be permitted to provide any such testimony. There is simply no scientific or medical basis for his opinion.

VI. Summary Judgment Standard

Fed. R. Civ. P. 56(a) provides that summary judgment shall be granted when the movant shows the absence of any genuine dispute as to any material fact and, for that reason, shows that he is entitled to judgment as a matter of law. The movant must demonstrate the absence of any genuine dispute as to any material fact by citing to particular parts of materials in the record, including depositions, documents and affidavits.[13] The movant may demonstrate entitlement to judgment as a matter of law by pointing out the nonmoving party's inability to produce evidence which, when taken as true for the purposes of the motion, would provide a

[13] Fed. R. Civ. P. 56(c)(1)(A).

legally sufficient basis upon which a reasonable jury might base a judgment in the nonmoving party's favor.[14]

Once a motion for summary judgment is made and properly supported, the burden shifts to the nonmoving party to come forward with evidence which demonstrates the essential elements of his claims.[15] In so doing, the nonmoving party establishes the existence of a genuine issue of material fact for trial. The nonmoving party must show that the evidence, when viewed in the light most favorable to him, is sufficient to enable a reasonable jury to render a verdict in his favor.[16] A party whose claims are challenged by a motion for summary judgment may not rest on the allegations of the complaint and must articulate specific factual allegations which meet his burden of proof.[17]

If the nonmoving party meets his burden of proof, summary judgment is inappropriate and the claims must be preserved for further proceedings. If, on the other hand, the nonmoving party does not meet his burden, the court must grant summary judgment in recognition of the implausibility of the claims at issue.[18]

All evidence submitted to the court in support of or in opposition to a motion for summary judgment must be of the sort which would be admissible at the trial of the matter.[19] "Metaphysical doubt" as to the existence of a genuine issue for trial is insufficient, as are

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[14] Celotex Corp v. Catrett, 477 U.S. 317, 2553 – 54 (1986); Duffy v. Leading Edge Products, Inc., 44 F.3d 308, 312 (5th Cir. 1995); Shotak v. Tenneco Resins, Inc., 953 F.2d 909, 913 (5th Cir. 1992), cert. denied 506 U.S. 832 (1992).
[15] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986); Little v. Liquid Air Corp., 37 F.3d 1069 (5th Cir. 1994).
[16] Celotex, 477 U.S. at 325.
[17] Id.
[18] Id. at 322.
[19] Fed. R. Civ. P. 56(c)(2); Salas v. Carptener, 980 F.2d 299, 305 (5th Cir. 1992) quoting Broadway v. City of Montgomery, 530 F.2d 657, 661 (5th Cir. 1976).

"unsubstantiated assertions" and "conclusory allegations[.]"[20] The court will construe all evidence in the light most favorable to the nonmoving party, but will not infer the existence of evidence not presented.[21]

VII. Novartis' motion for summary judgment

Novartis' motion for summary judgment asserts that plaintiff's claims against it in this suit should be dismissed on several bases: (1) plaintiff's strict liability claims for design defect, failure to warn, negligence and breach of express and implied warranties fail as a matter of law because the Louisiana Products Liability Act (La. R.S. 9:2800.52, et seq.) ("LPLA") provides the exclusive remedy for claims against manufacturers asserting claims for damages caused by the manufacturer's product;[22] (2) plaintiff lacks admissible evidence that she developed bisphosphonate-related ONJ; (3) assuming that plaintiff had evidence she suffered from bisphosphonate-related ONJ, she lacks admissible evidence that such condition was caused by Zometa; (4) assuming plaintiff can proffer some admissible causation evidence, it is insufficient to carry her burden of proof; (5) Novartis timely fulfilled its duty to warn of a potential association between Zometa and ONJ and plaintiff offers no evidence demonstrating that an earlier or different warning would have changed the course of her treatment with Zometa or her subsequent dental problems; (6) plaintiff has no evidence that Zometa was defectively designed; and (7) plaintiff has no evidence that there was an express warranty for Zometa.[23] The court finds that we need not address all of the seven (7) issues raised by Novartis in this motion, as explained fully below.

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[20] Little, 37 F.3d at 1075, citing Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986), Lujan v. National Wildlife Federation, 497 U.S. 871, 871-73 (1986); Hopper v. Frank, 16 F.3d 92 (5th Cir. 1994).
[21] Lujan, 497 U.S. at 888.
[22] La. R.S. 9:2800.52.
[23] R. 155-1 at pp. 1 – 2.

As argued by Novartis and acknowledged by plaintiff, the LPLA contains the exclusive theories of liability under which a plaintiff may recover damages for harms caused a manufacturer's product under Louisiana law.[24] Plaintiff must demonstrate the following elements in order to maintain a successful LPLA claim:

> (1) that the defendant is the manufacturer of the product at issue;
> (2) that the claimant's damage was proximately caused by a characteristic of the product;
> (3) that this characteristic made the product "unreasonably dangerous"; and
> (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else.[25]

As cited above, plaintiff's case-specific causation experts, Dr. Robert Marx and Dr. David Kim will not be permitted to testify in this case. Plaintiff offers no other evidence that she suffered from BIONJ and, as expressed above, her condition did not fit the parameters of BIONJ relied upon by Dr. Marx. Without admissible evidence demonstrating that plaintiff suffered from BIONJ, plaintiff is unable to meet her burden of proof under the LPLA, since she will not be able to show that her damage was proximately caused by a characteristic of the product.[26]

Although the court acknowledges that summary judgment is generally disfavored in the context of products liability cases, we find that, given the glaring failure of plaintiff's evidence with respect to her prima facie case under the LPLA, plaintiff's claims clearly fail as a matter of law.

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[24] La. R.S. 9:2800.52; Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254 (5th Cir. 2002).

[25] La. R.S. 9:2800.54(A).

[26] Jefferson v. Lead Industries Ass'n., Inc., 106 F.3d 1245 (5th Cir. 1997). To the extent that plaintiff's complaint asserts claims which are not within the scope of the LPLA and are not barred by that act's exclusive remedy provision, such claims must also fail because of plaintiff's lack of medical causation evidence. Demonstrating no causal connection between the allegedly defective product and any injury to plaintiff, she is unable to sustain any cause of action which arises from her interaction with that product.

Additionally, the court finds that Novartis' other outstanding litigation-wide Daubert motions are made moot by our findings as to these case-specific motions.[27] Finally, the court finds that Novartis' motion for oral argument on pending Daubert motions is, by the issuance of this memorandum ruling and forthcoming judgment, moot.[28]

The court will issue a judgment in conformity with these findings.

Alexandria, Louisiana
June 14, 2013

JAMES T. TRIMBLE, JR.
UNITED STATES DISTRICT JUDGE

[27] R. 96, 100, 104, 108, 113, 116, 120, 125, 128, 129, 132, 141, 146, 150.
[28] R. 178.