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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

John D'Agnese and Barbara D'Agnese,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation,

Defendant.

No. CV-12-00749-PHX-JAT

ORDER

Pending before the Court are: (1) Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83); (2) Defendant's Daubert Motion to Exclude Testimony of Dr. Mansfield (Doc. 84); (3) Defendant's Daubert Motion to Exclude Testimony of Dr. Vogel (Doc. 85); (4) Defendant's Daubert Motion to Exclude Testimony of Dr. Marx (Doc. 87); (5) Defendant's Daubert Motion to Exclude Testimony of Dr. Skubitz (Doc. 88); (6) Defendant's Daubert Motion to Exclude Testimony of Dr. Parisian (Doc. 89); (7) Defendant's Daubert Motion to Exclude Testimony of Dr. Wayne Ray (Doc. 90); and (8) Defendant's Daubert Motion to Exclude Testimony of Dr. Fletcher (Doc. 91).

I. BACKGROUND

This case is part of "Wave III" of a multidistrict litigation in the United States District Court for the Middle District of Tennessee (the "MDL Court"). In their Second Amended Complaint (Doc. 1), Plaintiffs allege that Defendant Novartis Pharmaceuticals Corporation ("Defendant" or "NPC") produces and markets the drugs Aredia® and

Zometa®.

Plaintiffs allege that Aredia® and Zometa® are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Plaintiffs allege that Aredia® was the first generation version of Zometa®. Plaintiffs further allege that these drugs cause and precipitate osteonecrosis of the jaw or maxilla bone. Plaintiffs allege that osteonecrosis is bone death of an area of the bone, which is a permanently disfiguring and painful condition, which can result in the complete loss of the patient's jaw bone.

Plaintiff John D'Agnese ("Mr. D'Agnese") used Aredia® and Zometa® to treat multiple myeloma bone disease, a disease that Mr. D'Agnese was diagnosed with in 1995. Mr. D'Agnese was also prescribed chemotherapy with cortiscosteroids, radiation treatments, and two stem cell implants to treat the multiple myeloma. Plaintiffs allege that Mr. D'Agnese suffered osteonecrosis of the jaw ("ONJ")[1] as a result of taking Aredia® and Zometa®. Plaintiffs assert that Mr. D'Agnese was given forty-seven doses of Aredia® from December 3, 1998 to May 28, 2002 and forty-two doses of Zometa® from June 28, 2002 to October 11, 2005.

After completion of pretrial proceedings, this case was transferred from the MDL Court to this Court.

Defendant now moves to exclude the testimony of seven of Plaintiffs' experts and the testimony of three of Plaintiffs' treating physicians pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rule of Evidence 702. The Court will discuss each Motion in turn.

[1] The Parties also use the acronyms "BONJ," "BRONJ," and "BIONJ" to refer to bisphosphonate-related osteonecrosis of the jaw. In discussing the opinions of certain experts, the Court also uses those terms.

II. LEGAL STANDARD

Federal Rule of Evidence 702

> establishes several requirements for admissibility: (1) the evidence has to "assist the trier of fact" either "to understand the evidence" or "to determine a fact in issue"; (2) the witness has to be sufficiently qualified to render the opinion:
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> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Primiano v. Cook, 598 F.3d 558, 563 -564 (9th Cir. 2010) (citing Fed. R. Evid. 702)).

> The requirement that the opinion testimony "assist the trier of fact" "goes primarily to relevance." For scientific opinion, the court must assess the reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance, but the inquiry is a flexible one. Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion. In sum, the trial court must assure that the expert testimony "both rests on a reliable foundation and is relevant to the task at hand."

Id. at 564 (citing *Daubert*, 509 U.S. at 591-597).

> "[T]he test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology." Under *Daubert*, the district judge is "a gatekeeper, not a fact finder." When an expert meets the threshold established by Rule 702 as explained in *Daubert*, the expert may testify and the jury decides how much weight to give that testimony.

Id. at 565 (internal citations omitted).

> "[M]edicine is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit." "Evidence-based medicine" is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." "Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment-a process that is difficult to quantify or even to assess qualitatively. Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties" to "mak[e] a sound judgment."
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> When considering the applicability of *Daubert* criteria to the particular case before the court, the inquiry must be flexible. Peer reviewed scientific literature may be unavailable because the issue may be too particular, new, or of insufficiently broad interest, to be in the literature. Lack of certainty is not, for a qualified expert, the same thing as guesswork. "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." "[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible.
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> "A trial court should admit medical expert testimony if physicians would accept it as useful and reliable," but it need not be conclusive because "medical knowledge is often uncertain." "The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof." Where the foundation is sufficient, the litigant is "entitled to have the jury decide upon [the experts'] credibility, rather than the judge."

Id. at 565-66 (internal citations omitted).

Finally, the District Court need only hold a *Daubert* hearing on medical evidence where the party challenging the expert's testimony "raises a material dispute as to the admissibility of expert scientific evidence . . . [at which point, the Court must] consider the conflicting evidence and make findings about the soundness and reliability of the methodology employed by the scientific experts." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 n.10 (9th Cir. 1995).

III. ANALYSIS

Defendant requests *Daubert* hearings on each challenged expert. Plaintiffs insist that no *Daubert* hearings are necessary and claim that Defendant simply wants to increase the expense and resources that Plaintiffs must expend in this case. *See* Doc. 135. Plaintiffs further argue that the Court can decide these issues on the Record and the Parties' briefs and that evidentiary hearings and oral argument are not necessary. *See id.*

A. Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83)

Defendant moves to exclude the testimony of three of Mr. D'Agnese's treating dental care providers from providing testimony that "Mr. D'Agnese's use of BPs caused him to develop a long-resolved jaw condition that he claims was ONJ."

The Court notes that much of Defendant's challenge of Mr. D'Agnese's treating physicians arises from the testimony Plaintiffs claimed the expert would make in their disclosure statement, rather than any actual opinions given by the treating physicians in this litigation. Defendant does not appear to dispute that these treating physicians may testify as percipient witnesses in this matter or that they may testify as to opinions formed during their treatment of Mr. D'Agnese.

Because it is undisputed that these treating physicians are able to offer some testimony in this matter and Defendant only challenges the expert's ability to offer an opinion on causation, the Court questions the necessity of *Daubert* hearings for these experts, both because it is not clear to the Court that these experts actually intend to offer

the opinions that Defendant challenges[2] and because, if Plaintiffs attempt to elicit testimony from these experts as to causation without laying the proper foundation for such testimony, a simple objection during trial would appear to serve the same purpose as a *Daubert* hearing while saving all Parties and the Court the expense of an evidentiary hearing to preview the testimony of witnesses that are going to testify despite the result of a *Daubert* hearing. Despite these reservations, the Court will consider whether Defendant has actually raised a material dispute as to the admissibility of *actual* opinions offered by these experts.

Defendant claims that the Court should exclude these treating physicians from offering such causation opinions under *Daubert* and Federal Rule of Evidence 702 for three reasons: (1) these treaters lack expertise regarding ONJ; (2) none of these treaters employed any methodology, let alone a scientifically reliable one, to conclude that Mr. D'Agnese's jaw condition was actually ONJ, or, if so, that Mr. D'Agnese's use of bisphosphonates actually caused his ONJ; and (3) the opinions Plaintiffs propose to offer from Drs. Green and Marischen do not fit Plaintiffs' case and will only serve to confuse the jury.

Further, Defendant argues that, because Drs. Green, Lines, and Marischen did not produce a report pursuant to 26(a)(2)(B), they are limited to opining solely as to matters regarding their treatment of Mr. D'Agnese. The Court notes that Plaintiffs' November 1, 2011 Disclosure Statement purports to comply with an Order issued by the MDL Court governing Wave 1-A cases. (Doc. 20-19 at n. 1). That Order (Doc. 2040 in Middle District of Tennessee Case No. MD 06-1760) appears to waive the requirement of an expert report pursuant to 26(a)(2)(B) for opinions by a plaintiffs' treating doctors concerning "the cause of the jaw problem allegedly experienced by plaintiff," opinions that were formed by the doctor "outside the scope of [the doctor's] treatment or

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[2] The Court is concerned that a ruling based on opinions that are not actually being offered by these witnesses would be an opinion on an issue that is not ripe and would be advisory.

evaluation of plaintiff," or for "use of the [doctor] at trial of that lawsuit to present evidence within the scope of Federal Rule of Evidence 702, 703, or 705" if Plaintiff disclosed to Defendant, in writing, the name and location of the doctor and stated the issues regarding which the disclosing party may elicit testimony from the doctor at trial (*Id.* at 1-2). In that Order, the MDL Court specifically stated that compliance with those rules, "shall constitute compliance with Rule 26(a)(2)(A)." (*Id.* at 2).

It is not clear to the Court whether this Order applied to Plaintiffs' "Wave III" case in the MDL or whether the Order applied notwithstanding the amendment to Rule 26 following the MDL Court's January 26, 2009 Order, but before Plaintiffs' 26(A)(2)(a) disclosure statement. Because the Parties have failed to brief these issues, this Court declines to address any possible issues regarding the sufficiency of Plaintiffs' disclosures regarding Mr. D'Agnese's treating doctors pursuant to Federal Rule of Civil Procedure 26. Accordingly, the Court will limit its review of the admissibility of the testimony of Mr. D'Agnese's treating doctors to issues identified by Defendant pursuant to *Daubert* and Federal Rule of Evidence 702. For these reasons, the Court presumes for the purposes of this Order that Plaintiffs have properly disclosed all of the opinions of their treating physicians pursuant to Federal Rule of Civil Procedure 26.

1. Dr. Green

In an August 15, 2011 disclosure statement, Plaintiffs stated that:

> Dr. Green is one of Mr. D'Agnese's dentists. His c.v. was produced at his deposition. He will testify to his treatment of Mr. D'Agnese and may use his expertise in this testimony. Dr. Green is expected to testify as to Mr. D'Agnese's dental condition during the applicable period and will use his expertise to describe bone and tooth conditions. He is also expected to testify he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ.

Doc. 20-19 at 3.

Defendant claims that Dr. Green should be precluded from offering causation opinions in this case because, during his May 19, 2010 deposition, he stated that (1) he

does not hold himself out to be an expert in causes of osteonecrosis of the jaw, (2) he conceded that he is unaware whether a cause and effect relationship between bisphosphonate exposure and ONJ has been reliably established, (3) he does not have the expertise to diagnose or treat ONJ; (4) he never observed any exposed necrotic bone in Mr. D'Agnese's mouth or impaired healing ability in his jaw; and (5) he does not know whether Mr. D'Agnese ever had ONJ.

Defendant argues that Dr. Green cannot be permitted to testify that "he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ." Defendant argues that, because Dr. Green is not an expert on the causes of ONJ, any such statement, is outside his expertise and thus is inadmissible pursuant to *Daubert* and Federal Rule of Evidence 702. Defendant further argues that this statement should be excluded pursuant to Federal Rule of Evidence 403 because it is unhelpful and would serve no purpose other than to mislead and confuse the jury.

In response, Plaintiffs argue that Dr. Green should be permitted to testify to his opinions regarding Mr. D'Agnese's medical condition. Plaintiffs point to testimony that Dr. Green gave during his May 19, 2011 deposition that (1) he was suspicious that Mr. D'Agnese had BIONJ, so he referred him to an oral surgeon; (2) he has been a dentist since 1963; (3) he reviewed the 2009 AAOMS guidelines on bisphosphonate related ONJ and Mr. D'Agnese's x-rays and charts; (4) he is familiar with periodontal disease; (5) he would not do implants for Mr. D'Agnese because of his exposure to bisphosphonates; (6) he was suspicious of the radiograph and history of bisphosphonate use; (7) Mr. D'Agnese's dental options are reduced because of his BIONJ; (8) as of March 2011, there was no multiple myeloma in Mr. D'Agnese's jaw; (9) he has no reason to disagree with the diagnosis of BIONJ for Mr. D'Agnese; (10) he did not learn of the relationship between ONJ and bisphosphonates until 2004 or 2005; (11) in an implant discussion at a study club, he learned of the dangers of implants and oral bisphosphonates; and (12) he has learned in continuing medical education that intravenous bisphosphonates, such as Aredia® and Zometa®, are too big a risk for dental implants.

From this, Plaintiffs argue that Dr. Green has specialized knowledge that the jury is entitled to hear on the cause of Mr. D'Agnese's disease. Specifically, Plaintiffs argue that Dr. Green can discuss periodontal disease, finding no myeloma in the jaw, and any other dental problems, and potentially rule them out as causes of ONJ.

Plaintiffs finally argue that the Court should allow all of Mr. D'Agnese's "dental treaters" to testify as to their cause opinions. With regard to Dr. Green, the basis of Plaintiffs' contention that the Court should allow Dr. Green to testify as to his "cause" opinion is unclear to the Court. At no time do Plaintiffs refer the Court to a disclosure or other testimony of Dr. Green that Aredia® and Zometa® caused Mr. D'Agnese's ONJ. Further, Plaintiffs do not dispute Defendant's contention that Dr. Green testified that he is not able to diagnose ONJ, or to identify the causes of ONJ, or to testify that bisphosphonates cause ONJ. Defendant specifically asks the Court to exclude Dr. Green's opinion, that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ. Plaintiffs have failed to present any evidence that Dr. Green is qualified to make such an opinion. There is no question that, if Plaintiffs sought to elicit the statement that Dr. Green had reason to believe that Zometa® caused Mr. D'Agnese's ONJ, they would have to establish that he has the requisite expertise to render that opinion. Plaintiffs have not done so and, thus, they cannot do the inverse. Further, Plaintiffs have failed to establish the relevance of any statement from Dr. Green that he has no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ.

Accordingly, the Motion to Exclude the testimony of Plaintiffs' non-retained experts is granted to the extent that it seeks to exclude Dr. Green's opinion that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ. Because this is the only opinion actually given by Dr. Green that Defendant challenges, the Court limits its Order to such opinion. Defendant has not offered any evidence that Dr. Green indicated in his deposition testimony, or elsewhere, that he intends to testify that Plaintiffs had ONJ or that Zometa® or Aredia® caused ONJ. However, to the extent Plaintiffs attempt to elicit testimony from Dr. Green to that effect, Defendant may make

the appropriate objection at trial. This Order is not intended to limit any testimony of Dr. Green regarding the *facts* or other opinions that he may testify to as a percipient witness should the proper foundation for such facts be laid by Plaintiffs. *See Primiano v. Cook*, 598 F.3d 558 (9th Cir. 2010) ("Where the foundation is sufficient, the litigant is 'entitled to have the jury decide upon [the experts'] credibility, rather than the judge.'") (internal citation omitted).

2. Dr. Lines

In an August 15, 2011 disclosure statement, Plaintiffs stated that:

> Dr. Limes [sic] is Mr. D'Agnese's Oral and Maxillofacial surgeon who diagnosed him with Bisphosphonate Related ONJ. His c.v. was produced at his deposition. He will testify to his treatment of Mr. D'Agnese and may use his expertise in this testimony. He is expected to testify, *inter alia*, Mr. D'Agnese's ONJ was caused and/or consistent with BONJ, and to his symptoms and side effects of treatment. He is further expected to testify that ONJ is treated differently from BONJ.

(Doc. 20-19 at 2-3).

Defendant claims that Dr. Lines should be precluded from offering causation opinions in this case because, during his May 25, 2011 deposition, he stated that (1) he does not hold himself out to be an expert in ONJ or intravenous bisphosphonates, (2) he has never researched ONJ, ONJ risk factors, bisphosphonates, published any articles, and does not know if a cause and effect relationship between bisphosphonate exposure and ONJ has been proven; (3) in his practice, he has never diagnosed the cause of ONJ in a bisphosphonate patient; (4) although, in his treatment of Mr. D'Agnese, he assumed Mr. D'Agnese had an issue with osteonecrosis, it was just an assumption; (5) Dr. Lines conceded that necrotic bone can be caused by infection, osteomyelitis and radiation and that loose teeth and bone loss can be caused by osteoporosis and periodontitis. Dr. Lines did not perform biopsies, histopathies, or cultures or attempt to rule out any alternative (non-BP) causes of Mr. D'Agnese's jaw problem; (6) Dr. Lines testified that he is not

offering expert testimony on the causation of osteonecrosis, but his working assumption was that Mr. D'Agnese had osteonecrosis secondary to bisphosphonates; and (7) Dr. Lines agreed that Mr. D'Agnese's presentation did not meet the American Association of Oral and Maxillofacial Surgeons' ("AAOMS") criteria for a clinical diagnosis of bisphosphonate-related ONJ.

Defendant argues that Dr. Lines' testimony regarding whether Mr. D'Agnese had ONJ or what caused that ONJ should be excluded because (1) he disclaimed expertise in both osteonecrosis and BPs; and (2) Dr. Lines is not qualified to opine that BPs can generally cause ONJ because he has offered no evidence of academic or professional expertise regarding ONJ etiology and has never diagnosed the cause of ONJ in a bisphosphonate patient.

In response, Plaintiffs argue that (1) Dr. Lines is a board certified oral surgeon with over twenty-one years of experience as an oral/maxillofacial surgeon and has seen "a score" of cases of BIONJ; (2) he has given talks to other physicians on bisphosphonates and prevention of ONJ; (3) he testified that he knows that radiation is a cause of ONJ and there is an association between ONJ and bisphosphonates, but is not sure of all of the causes of ONJ, (4) he testified that of roughly 20 or 30 patients with ONJ, roughly 6 to 10 were taking bisphosphonates; and (5) he explained, in detail, his treatment of Mr. D'Agnese and the reasons for his treatment decisions.

From this, Plaintiffs argue that Dr. Lines must be able to testify that Mr. D'Agnese had ONJ and it was caused by bisphosphonates. Plaintiffs also argue, without citation to the record, that "Dr. Lines easily falls into the category of medical treaters who are experts in BIONJ." (Doc. 98 at 14).

Neither Plaintiffs nor Defendant actually discuss any opinions by Dr. Lines that Mr. D'Agnese had ONJ or BIONJ. To the extent that Dr. Lines testified that he treated Mr. D'Agnese on the assumption that he had BIONJ or ONJ with specific reasons why he proceeded with treatment based on those assumptions, Defendant has not challenged Dr. Lines' underlying methodology or scientific reasoning in making such assumptions.

Accordingly, the Court finds that Plaintiffs have failed to make a showing that Dr. Lines can testify that Mr. D'Agnese had ONJ or BIONJ. Defendant has failed to make a showing that Dr. Lines cannot testify as to the facts of his treatment of Mr. D'Agnese, including his working assumption that Mr. D'Agnese had ONJ and the further assumption that bisphosphonates caused that ONJ. Defendant has failed to argue or show that these assumptions were not based on reliable principles and methods. To the extent that Defendant challenges those opinions, such challenge goes to the weight of Dr. Lines' testimony, as his failure to categorically determine Mr. D'Agnese's condition and/or the cause of that condition does not render his working assumptions about that condition non-scientific speculation.[3] *See Primiano*, 598 F.3d at 564, 566 ("[T]he test under

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[3] Under similar facts, the Ninth Circuit Court of Appeals addressed this issue as follows:

> The law grants the district court the same broad latitude in determining how to determine reliability as it enjoys when deciding whether that expert's relevant testimony is reliable. *Kumho*, 562 U.S. 137, 119 S.Ct 1167, 1176. Furthermore, experts are permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observations, so long as they have a reliable basis in the knowledge and experience of the discipline. *Daubert*, 509 U.S. at 592, 113 S.Ct. 2786. What is required is a "fit," a determination that the proposed testimony is relevant to the task at hand, logically advancing a material aspect of the proposing party's case. *Daubert v. Merrell Dow Pharm.*, Inc., 43 F.3d 1311, 1315 (9th Cir.1999). Here, the trial court focused on the fact that Dr. Strange was Huff's treating physician, with knowledge of Huff's condition before the fall and after it. The district judge allowed Dr. Strange to testify in order to establish whether his medical findings were consistent with what was related to him by Huff. In concluding that Dr. Strange's conclusions as to the cause of Huff's fall would go to weight, and not to admissibility, the district judge pointed out that Dr. Strange clearly delimited his testimony, candidly admitting under cross-examination

Daubert is not the correctness of the expert's conclusions but the soundness of his methodology") (internal citation omitted).

Accordingly, the Motion to Exclude the testimony of Plaintiffs' non-retained experts is denied as to Dr. Lines' opinions. Defendant has not offered any evidence that Dr. Lines indicated in his deposition testimony, or elsewhere, that he intends to testify that Mr. D'Agnese had ONJ or that Zometa® or Aredia® caused ONJ. However, to the extent Plaintiffs' attempt to elicit testimony from Dr. Lines to that effect, Defendant may make the appropriate objection at trial. This Order is not intended to limit any testimony of Dr. Lines regarding the *facts* or other opinions that he may testify to as a percipient witness should the proper foundation for such facts be laid by Plaintiffs.

3. Dr. Marischen

In an August 15, 2011 disclosure statement, Plaintiffs stated that:

> Dr. Marischen is one of Mr. D'Agnese's dentists. His c.v. was produced at his deposition. He will testify to his treatment of Mr. D'Agnese and may use his expertise in this testimony. Dr. Marischen is expected to testify as to Mr. D'Agnese's dental condition during the applicable period and will use his expertise to describe bone and tooth conditions. He is also expected to testify he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ.

> that after an extensive differential diagnosis he could not point to an objective medical basis for Huff's pain. The fact that all commonly accepted diagnostic tests-x-rays, lumbar CT scan, EMG, MRI, dermatomal distribution test-failed to reveal any precise physiological cause of Huff's leg complaints does not reduce his conclusions based on that evidence to non-scientific "speculation." Generating hypotheses and testing them to see if they can be falsified is the distinguishing characteristic of science. *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786. The district judge's ruling that the qualified conclusion reached by Dr. Strange would be left for the jury to believe or disbelieve was not an abuse of discretion.

Huff v. Wal-Mart Stores, Inc., 203 F.3d 831, 1999 WL 1206845, at *2 (9th Cir. 1999).

Doc. 20-19 at 2.

Defendant argues that Dr. Marischen should be precluded from offering causation opinions in this case because Dr. Marischen was not deposed in this case and Plaintiffs cannot meet their burden to show that Dr. Marischen is an expert in diagnosing ONJ or the causes of ONJ. Defendant argues that, because he has no expertise, Dr. Marischen should be precluded from offering the opinion that "he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ."

In Response, Plaintiffs state that "Dr. Marischen is a prosthodontist whose medical records reflect he treated Mr. D'Agnese as a BIONJ patient." (Doc. 98 at 10). Plaintiffs further state that Dr. Marischen has specialized knowledge that the jury is entitled to hear on the cause of Mr. D'Agnese's disease.

Defendant specifically asks the Court to exclude Dr. Marischen's opinion that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ. Plaintiffs have failed to present any evidence that Dr. Marischen is qualified to make such an opinion. There is no question that, if Plaintiffs sought to elicit the statement that Dr. Marischen had reason to believe that Zometa® caused Mr. D'Agnese's ONJ, they would have to establish that he has the requisite expertise to render that opinion. Plaintiffs have not done so and, thus, they cannot do the inverse. Further, Plaintiffs have failed to establish the relevance of any statement from Dr. Marischen that he has no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ.

Accordingly, the Motion to Exclude the testimony of Plaintiffs' non-retained experts is granted to the extent that it seeks to exclude Dr. Marischen's opinion that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ. However, because Dr. Marischen was not deposed in this case, and Plaintiffs have not presented any affidavit or other evidence containing Dr. Marischen's proposed testimony, the Court is unable to ascertain what Dr. Marischen's opinions actually are or the basis for those opinions. Neither party has offered any evidence that Dr. Marischen intends to testify that Mr. D'Agnese had ONJ or that Zometa® or Aredia® caused ONJ. However,

to the extent Plaintiffs attempt to elicit testimony from Dr. Marischen to that effect, Defendant may make the appropriate objection at trial. This Order is not intended to limit any testimony of Dr. Marischen regarding the *facts* or other opinions that he may testify to as a percipient witness should the proper foundation for such facts be laid by Plaintiffs.

B. Defendant's Daubert Motion to Exclude Testimony of Dr. Mansfield (Doc. 84)

Dr. Mansfield is an oral/maxillofacial specialist, who was retained by Plaintiffs to offer expert testimony in this case. Dr. Mansfield's proposed testimony is based on his thirty years of experience as an oral/maxillofacial surgeon, his examination of Mr. D'Agnese's medical records, scientific literature, and his own examination of Mr. D'Agnese. Dr. Mansfield wrote a letter to Mr. D'Agnese's counsel summarizing his opinions regarding Mr. D'Agnese's condition. Plaintiffs assert that this letter is Dr. Mansfield's "Rule 26 report." (Doc. 98 at 4). Dr. Mansfield was also deposed in this case.

Defendant argues that Dr. Mansfield's opinion that Aredia® and Zometa® caused Mr. D'Agnese's ONJ must be excluded under Federal Rule of Evidence 702 and *Daubert* because: (1) Dr. Mansfield admitted that Mr. D'Agnese's jaw condition is most likely something other than ONJ; (2) Dr. Mansfield failed to consider admittedly plausible alternative causes, let alone reliably rule them out, so he did not employ a differential diagnosis or any other reliable methodology for determining the cause of Mr. D'Agnese's jaw condition; and (3) Dr. Mansfield conceded that the purported basis for his opinion that bisphosphonates caused Mr. D'Agnese's alleged ONJ is scientifically unreliable.

It is undisputed that, at the time Dr. Mansfield examined Mr. D'Agnese, in July 2011, there was no clinical evidence that he had ONJ on that date. It is disputed whether Mr. D'Agnese suffered from ONJ from 2005 to 2007.

In his September 1, 2011 deposition, Dr. Mansfield testified that he has treated 150 to 200 cases of ONJ and has diagnosed approximately 10 to 12 of those cases as

being caused by bisphosphonates. Dr. Mansfield further testified that determining that ONJ is caused by bisphosphonates is a diagnosis by exclusion because the disease and the process cannot be biopsied. Dr. Mansfield testified that he makes a diagnosis of ONJ caused by bisphosphonates based on exclusion, history, and presentation. Dr. Mansfield testified that a proper diagnosis of BIONJ has three criteria: (1) exposure to bisphosphonates; (2) exposed bone for more than eight weeks in the jaw; and (3) no history of radiation therapy to the jaw. When questioned as to whether Mr. D'Agnese had exposed bone for more than eight weeks in the jaw, Dr. Mansfield explained that by Mr. D'Agnese's own verbal history, he had exposed bone for close to eight weeks, but there was no evidence of necrotic bone for eight weeks in the medical records.

Dr. Mansfield further explained that it was not clear from the medical records whether Mr. D'Agnese had radiation to the jaw when he was given radiation eight years before developing his jaw problems. Dr. Mansfield did opine that the quantity of radiation given to Mr. D'Agnese eight years before he developed problems with his jaw likely did not have a significant impact on Mr. D'Agnese's jaw when he developed those issues.

Defendant's first two challenges to Dr. Mansfield's testimony as to causation are that Dr. Mansfield admitted that Mr. D'Agnese's jaw condition is most likely something other than ONJ and that Dr. Mansfield failed to consider admittedly plausible alternative causes, let alone reliably rule them out, so he did not employ a differential diagnosis or any other reliable methodology for determining the cause of Mr. D'Agnese's jaw condition.

With regard to their first argument, Defendant cites to testimony by Dr. Mansfield indicating that Mr. D'Agnese's jaw condition would have been consistent with an infection. With regard to their second argument, Defendant cites to testimony that Dr. Mansfield did not rule out every other possible cause identified by Defendant of Mr. D'Agnese's condition. Nothing in this testimony renders Dr. Mansfield's opinion that Mr. D'Agnese's jaw condition was consistent with bisphosphonate-related ONJ

unreliable. Dr. Mansfield's failure to definitively conclude that Mr. D'Agnese's jaw condition was caused by bisphosphonates does not convert his opinions that Mr. D'Agnese's jaw condition could have been caused by bisphosphonates and that Mr. D'Agnese's case meets the three criteria for bisphosphonate-related ONJ to non-scientific "speculation."

Dr. Manfield's proposed testimony is relevant to the issue of causation in this case and advances a material aspect of Plaintiffs' case. Although Defendant may disagree with Dr. Mansfield's opinions, Defendant can cross-examine Dr. Mansfield and the jury can decide on his credibility. *See Primiano*, 598 F.3d at 566 ("Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible.").

Finally, Defendant asserts that Dr. Mansfield should not be permitted to testify as to causation because "Dr. Mansfield conceded that the purported basis for his opinion that bisphosphonates caused Mr. D'Agnese's alleged ONJ is scientifically unreliable." In fact, Defendant challenges Dr. Mansfield's reliance on Mr. D'Agnese's statement that he had exposed bone for more than eight weeks in his jaw in establishing the second element of a BIONJ diagnoses. Defendant appears to suggest that doctors can only make a diagnosis based on medical phenomena that the doctor himself witnesses and may not take their patient's subjective complaints into account when making a diagnosis. This simply cannot be the case. "A trial court should admit medical expert testimony if physicians would accept it as useful and reliable, but it need not be conclusive because medical knowledge is often uncertain." *Primiano*, 598 F.3d at 565-66 (internal quotation omitted). Certainly, physicians often rely on their patient's subjective complaints in making a diagnosis of their ailments. To the extent that Defendant seeks to challenge Mr. D'Agnese's credibility in the information that he gave to Dr. Mansfield, which resulted in a "diagnosis" that Mr. D'Agnese's symptoms were consistent with BIONJ, such challenge can be made before the jury.

The Court finds that Defendant has failed to raise a genuine dispute as to the

admissibility of Dr. Mansfield's testimony and, thus, their request for a *Daubert* hearing, and their Motion to Exclude Dr. Mansfield's testimony is denied.

C. Defendant's Daubert Motion to Exclude Testimony of Dr. Vogel (Doc. 85)

Dr. Vogel is an oncologist and hematologist who practiced medicine for more than thirty-five years and is an Associate Professor at the Mount Sinai School of Medicine.

In deciding Motions for Summary Judgment in the MDL, the MDL Court found that Dr. Vogel's testimony concerning general causation and the scientific and medical accuracy of warnings given by Novartis were admissible under Federal Rule of Evidence 702 and *Daubert*. (*See* Doc. 85-7 and Doc. 85-8). Defendant does not challenge those rulings, but rather argues that Dr. Vogel's proposed testimony concerning (1) the alleged corporate behavior of Novartis, (2) the delay and failure in transmission of certain information impacting a large number of patients, and (3) the benefit of pretreatment dental screening should be precluded under Rule 702 and *Daubert*. The MDL Court declined to rule on whether such testimony should be admitted under Rule 702 and *Daubert*.

Defendant argues that, "[b]ased on his review of a select few corporate documents that plaintiffs' counsel provided him, Dr. Vogel criticizes NPC's response to reports of ONJ in patients receiving Zometa®, including how it revised its labeling." Defendant argues that these opinions should be excluded because Dr. Vogel has no first-hand knowledge of the circumstances and brings no scientific or other technical expertise to bear on the testimony. Defendant argues that this opinion is both subjective and speculative. Defendant further argues that these opinions would not assist the jury because the opinions merely reiterate arguments based on inferences that can be drawn by laypersons.

To support this argument, Defendant points to testimony that Dr. Vogel gave during his April 2, 2009 deposition that he is not an expert regarding drug labeling, he is not an expert in FDA regulation of pharmaceutical companies, he did not review and is

not familiar with the relevant FDA regulations, and he was not aware of certain communications between the FDA and Defendant regarding the Zometa® label. Accordingly, Defendant requests that the Court preclude "Dr. Vogel from criticizing NPC's labeling."

Defendant next argues that Dr. Vogel's opinions regarding NPC's corporate conduct, including NPC's knowledge and intent are not the proper subject of expert testimony. Specifically, Defendant argues that the Court should preclude Dr. Vogel from offering any of the following opinions: (1) Defendant misrepresented causation evidence, (2) Defendant referenced corticosteroids as potential risk factors for ONJ in the warnings on its label to misdirect the focus of medical attention away from the jaw area; (3) Defendant minimized the incidence rate of ONJ; (4) Defendant knew and failed to communicate that ONJ occurs in a patient after fewer infusions of Zometa® than of Aredia® and (5) Defendant knew and failed to communicate that a decrease in the duration, dose, and/or frequency of therapy decreases the incidence of ONJ.

Defendant argues that these opinions must be precluded because they are not based on scientific, technical, or other specialized knowledge, Dr. Vogel has no experience that would qualify him to opine on the conduct of a pharmaceutical company and is no more competent than the jury to evaluate the emails cited in his reports.

Defendant next argues that Dr. Vogel's opinion that preventative dental measures taken prior to initiating Aredia® and Zometa® therapy would reduce the incidence of ONJ. First, Defendant argues the opinion is irrelevant because it does not "fit" the facts of this case. Defendant argues that, because Mr. D'Agnese's medical oncologist, Dr. Olshan performed a dental examination on Mr. D'Agnese before bisphosphonate therapy began and Dr. Mansfield testified that a warning was irrelevant in Mr. D'Agnese's case because Dr. Olshan conducted a thorough medical examination.

Second, Defendant argues that Dr. Vogel's methodology in support of this opinion is not scientifically reliable because (1) the sole basis for his opinion was a publication regarding a retrospective study attempting to analyze the benefits of dental monitoring of

patients while on bisphosphonates, which is not the type of evidence that experts in the field would rely upon to determine the effectiveness of pretreatment dental screenings, (2) Dr. Vogel's opinion conflicts with Dr. Marx's opinion that it is not clear whether pretreatment dental screenings are effective in reducing the incidence of ONJ.

Defendant next argues that Dr. Vogel's opinions regarding the incidence of ONJ are irrelevant and are based on insufficient facts and data. Defendant argues that Dr. Vogel's opinion that, in publications and correspondence, Defendant minimized the incidence of ONJ in patients on Aredia® and Zometa® because the incidence rate is generally five percent or above should be precluded because: (1) it is not relevant as the correspondence and publications that Dr. Vogel relies on post-date 2005, the year that Mr. D'Agnese received his last infusion of Zometa® and thus, this evidence did not exist when Mr. D'Agnese was being prescribed Zometa®; (2) even if this information were relevant, it is based on insufficient facts and data and is false based on randomized, double blind, controlled studies that find the incidence rate of ONJ in Zometa® patients is one percent that Dr. Vogel failed to account for in his conclusions; (3) the publications that Dr. Vogel relies on do not support his conclusion, (4) Dr. Vogel's methodology is internally inconsistent because he selectively relies on certain studies and personal experience while disregarding studies that clearly undermine his conclusions.

Defendant next argues that Dr. Vogel's opinion that "a reduced dosing schedule has shown equal efficacy and less risk" and Dr. Vogel's suggestion that Defendant improperly failed to disseminate information about alternative dosing schedules should be precluded because (1) Dr. Vogel is not qualified to offer an opinion on this issue as he admittedly lacks knowledge of the FDA's role in the regulation and labeling of prescription drugs because he does not know what information the FDA permits Defendant to provide to the medical community about Aredia® and Zometa®; and (2) Dr. Vogel's opinions are not relevant because he relies on a single retrospective study that involved only 106 myeloma patients, which was published a year and a half after Mr. D'Agnese stopped taking Zometa®, and does not address whether Defendant should have

advised prescribing physicians of a different dosing schedule in 2002 through 2005.

Finally, Defendant argues that Dr. Vogel is unqualified to offer the opinion that BPs are more likely to accumulate in the jaw than in other bones due to higher remodeling rates and higher uptake of bisphosphonates because (1) Dr. Vogel is not a bone biologist or pathologist; and (2) Dr. Vogel concedes he does not have the expertise to explain his mechanism hypotheses to the jury.

In Response,[4] Plaintiffs argue that other courts in other districts have ruled on

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[4] Plaintiffs filed one Response to Defendant's *Daubert* motions regarding Dr. Marx, Dr. Fletcher, Dr. Ray, Dr. Skubitz, and Dr. Vogel. In that Response, Plaintiffs attempt to "incorporate by reference" "the entirety of the *Daubert* opposition briefs and all exhibits filed in [the MDL case] in the 'Wave I-A' cases, filed on September 1, 2010, in the 'Wave I-B' cases, filed on November 22, 2010 in the 'Wave I-C' cases, filed on June 20, 2011 in the 'Wave II' cases, filed on November 30, 2011 in the Wave 'III' cases filed on September 16, 2012 in the Wave 'IV' cases, and oppose [Defendant's] current motion to exclude these witnesses for those and the following reasons." (Doc. 104 at 2). Plaintiffs have not attached any of these "oppositions" to their Response. Plaintiffs rely on Federal Rule of Civil Procedure 10(c) for this "incorporation by reference."

First, Federal Rule of Civil Procedure 10(c) does not apply to arguments in certain motions being incorporated by reference into new motions. Rather, Federal Rule of Civil Procedure 10(c) allows statements in *pleadings* to be adopted by reference in any other pleadings or motions. *See* Fed.R.Civ.P. 10(c); Fed.R.Civ.P. 7(a) (defining pleadings as a complaint, answer to a complaint, answer to a counterclaim designated as a counterclaim, an answer to a crossclaim, a third-party complaint, an answer to a third-party complaint and a reply to an answer).

Second, this attempt to incorporate various documents by reference that include arguments related and unrelated to the current issues before the Court circumvents this Court's local rules governing page limits.

Finally, this Court is not going to dig through various documents (copies of which have not even been provided by Plaintiffs) in order to determine what arguments in those other oppositions Plaintiffs believe may or may not be relevant to the issues *currently* before the Court. It is Plaintiffs obligation to oppose Defendant's arguments and not this Court's obligation to attempt to ascertain what arguments from other motions Plaintiffs may be trying to make again. *See Orr v. Bank of America,* 285 F.3d 764, 775 (9th Cir. 2002) (internal quotation omitted) ("Judges need not paw over the files without assistance from the parties.")); *Indep. Towers of Wash. v. Washington,* 350 F.3d 925, 929 (9th Cir.

Daubert motions in other cases that were part of the MDL and have admitted at least some of the testimony challenged by Defendant in the motions before this Court.[5] Plaintiffs do not make any arguments in response to Defendant's challenges to Dr. Vogel's testimony nor do they explain why Dr. Vogel's testimony should be admitted under Federal Rule of Evidence 702.

Accordingly, Defendant has raised material disputes as to the admissibility of the challenged testimony of Dr. Vogel and, thus, the Court must hold a *Daubert* hearing to determine if Dr. Vogel's opinions on the matters challenged by Defendant are admissible under Federal Rule of Evidence 702. If Plaintiffs do not intend to offer the *challenged* testimony of Dr. Vogel, Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Vogel's testimony will be vacated, Dr. Vogel will not be permitted to testify on the challenged subjects at trial, and the *Daubert* motion will be denied as moot.

2003) ("[J]udges are not like pigs, hunting for truffles buried in briefs.'") (citation omitted).

If Plaintiffs required a page extension to respond to Defendant's argument on the *current* Motions pending before the Court, they could have either filed separate responses to each *Daubert* Motion or could have requested a page extension from the Court. Plaintiffs chose to do neither and erroneously relied on Federal Rule of Civil Procedure 10(c) to incorporate arguments in various other oppositions that are not in this Court's record by reference into the current Response.

Accordingly, the Court has not considered any of the oppositions that Plaintiffs attempted to "incorporate by reference" that were filed in the MDL.

[5] Although the Court gave Plaintiffs the opportunity to explain whether or not res judicata would somehow apply to the challenged testimony of Dr. Vogel, Plaintiffs have not made any argument that res judicata would apply to the opinions *challenged* by Defendant.

D. Defendant's Motion to Exclude Testimony of Dr. Marx (Doc. 87)

Dr. Marx is Chief of Oral and Maxillofacial Surgery at the University of Miami Health System and is involved in ongoing research concerning bisphosphonates and osteonecrosis of the jaw. He was one of the earliest physicians to allege a connection between bisphosphonates and ONJ and, in 2003, was invited by Defendant to participate in more than one advisory board meeting on ONJ. (Doc. 87-6). Plaintiffs intend to present testimony of Dr. Marx as a case-wide general expert and do not intend to present case specific opinions of Dr. Marx regarding Mr. D'Agnese's jaw problems.

In the MDL, Defendant filed a Motion to Exclude Litigation-Wide Testimony of Plaintiffs' Expert Dr. Robert Marx. (Doc. 87-6) In that Motion, Defendant challenged Dr. Marx's testimony regarding (1) the causal connection between Aredia® and Zometa® and ONJ, (2) treatment and preventative measures for ONJ, (3) alleged misconduct by Defendant, which Dr. Marx considers to be taken in "bad faith," (4) whether certain patients in the Aredia®/Zometa® clinical trials likely had bisphosphonate-induced ONJ, and (5) criticisms of certain aspects of those clinical trials. (*Id.*).

The MDL Court ruled, that for the purposes of deciding summary judgment, Dr. Marx's testimony regarding the causal connection between Aredia® and Zometa® and ONJ and treatment and preventive measures for ONJ should be admitted pursuant to Federal Rule of Evidence 702. (*Id.*). The MDL Court declined to rule on whether Dr. Marx's opinions regarding Defendant's bad faith or his opinions concerning clinical trials should be precluded pursuant to Rule 702. (*Id.*).

Defendant argues that Dr. Marx's testimony regarding the adequacy of Defendant's warnings are irrelevant and do not fit the facts of Mr. D'Agnese's case because (1) Mr. D'Agnese was first prescribed Aredia® in 1998 before any associations between ONJ and BPs became known or knowable according to Dr. Marx and (2) even after he was warned of the potential risk of ONJ by his prescribing oncologist, Dr. Olshan, Mr. D'Agnese opted to continue using Zometa®.

Defendant next argues that Dr. Marx's opinions regarding preventive dental measures should be excluded because they do not fit the facts of Mr. D'Agnese's case because prior to initiating Zometa® therapy, Dr. Olshan performed a detailed examination of Mr. D'Agnese's oral cavity and, from that examination, Dr. Olshan determined that there was no need for Mr. D'Agnese to undergo an invasive surgery. Defendant argues that Dr. Mansfield testified that a warning regarding a pre-prescription dental exam is irrelevant in Mr. D'Agnese's case given Dr. Olshan's examination. Defendant argues that, based on this, a warning to avoid invasive dental procedures while on BP therapy is also irrelevant. Defendant argues that Dr. Marx's opinions regarding preventative dental measures should also be excluded because Dr. Marx has no scientifically reliable basis upon which to opine that dental treatment measures actually prevent BP patients from developing ONJ because he stated that the jury is still out in terms of controlled data on that issue.

Defendant next argues that Dr. Marx offers the opinion that Defendant ignored evidence that bisphosphonates caused ONJ and, thus acted in bad faith. Defendant argues that this opinion about Defendant's state of mind is outside the bounds of his expertise and is inadmissible speculation.

Defendant next argues that Dr. Marx offers the opinion that NPC's clinical trials were a serious deviation of proper research data recording and jaw and mouth examinations were not routinely performed as part of the trial. Defendant argues that this opinion should be precluded because Dr. Marx lacks the expertise to evaluate the design and conduct of these trials and admits that he used hindsight in reaching the opinions. Defendant argues that Dr. Marx lacks the relevant expertise because he admits that he never planned or managed any clinical trials relating to bisphosphonates, is not an expert in the FDA's regulation of drug companies, and has never been involved in putting together a New Drug Application for submission to FDA. Defendant further argues that Dr. Marx is unqualified to offer this opinion because he is not a medical doctor, does not prescribe BPs and does not treat patients who require BPs.

Defendant next argues that this opinion regarding clinical trials should be excluded because Dr. Marx does not offer any evidence that before or during the period when the trials were designed or conducted Defendant knew or had reason to know that ONJ was a possible side effect of Aredia® or Zometa® therapy.

Defendant next argues that Dr. Marx's opinion that five patients in the clinical trials had bisphosphonate-related ONJ are post-hoc diagnoses that do not satisfy one of the factors of a BIONJ diagnoses, namely that the patient had exposed bone lasting more than eight weeks. Defendant argues that this demonstrates that Dr. Marx's methodology in reaching a diagnosis of ONJ is applied inconsistently and is unreliable.

Defendant finally argues that Dr. Marx's general causation testimony is unreliable and that Dr. Marx's opinions about the biological mechanism by which BP drugs allegedly cause ONJ fails because Dr. Marx lacks necessary expertise and the testimony is unreliable. With regard to these latter two challenged opinions, the Court finds that the MDL Court has already considered these issues and ruled that such testimony is admissible when it stated that Dr. Marx's testimony regarding the causal connection between Aredia® and Zometa® and ONJ and treatment and preventive measures for ONJ should be admitted pursuant to Federal Rule of Evidence 702. Defendant has failed to present any evidence to the Court that the MDL Court did not consider the challenges Defendant now makes, or if the MDL Court did not consider those challenges, the reasons Defendant did not make such challenges in its earlier motion. These challenges do not appear to be specific to Mr. D'Agnese's case, but rather appear to challenge Dr. Marx's case wide testimony regarding the causal connection between bisphosphonates and ONJ. Accordingly, Defendant has presented no convincing reason for this Court to reconsider the MDL Court's decision regarding the admissibility of Dr. Marx's testimony regarding the causal connection between Aredia® and Zometa® and ONJ and treatment and preventive measures for ONJ and such testimony should be admitted pursuant to Federal Rule of Evidence 702.

With regard to the other challenged portions of Dr. Marx's testimony, Plaintiffs

argue that other courts in other districts have ruled on *Daubert* motions in other cases that were part of the MDL and have admitted at least some of the testimony challenged by Defendant in the motions before this Court.[6] Plaintiffs do not make any arguments in response to Defendant's challenges to Dr. Marx's testimony nor do they explain why Dr. Marx's testimony should be admitted under Federal Rule of Evidence 702.

Accordingly, Defendant has raised material disputes as to the admissibility of the challenged testimony of Dr. Marx, with the exception of the challenged testimony concerning general causation and biological mechanism, and, thus, the Court must hold a *Daubert* hearing to determine if Dr. Marx's opinions on the matters challenged by Defendant are admissible under Federal Rule of Evidence 702. If Plaintiffs do not intend to offer the *challenged* testimony of Dr. Marx, Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Marx's testimony will be vacated, Dr. Marx will not be permitted to testify on the challenged subjects at trial, and the *Daubert* motion will be denied as moot.

E. Defendant's Motion to Exclude Testimony of Dr. Skubitz (Doc. 88)

Dr. Skubitz is a medical oncologist on the faculty of the University of Minnesota Medical School. Plaintiffs intend to present testimony of Dr. Skubitz as a case-wide general expert and do not intend to present case specific opinions of Dr. Skubitz regarding Mr. D'Agnese's jaw problems.

In the MDL, Defendant filed a Motion to Exclude Testimony of Plaintiffs' Expert Dr. Keith Skubitz. (Doc. 104-15) In that Motion, Defendant challenged Dr. Skubitz's testimony regarding (1) general causation, (2) scientific and medical accuracy of warnings given by Defendant (3) extending the dosing interval for patients with

[6] Although the Court gave Plaintiffs the opportunity to explain whether or not res judicata would somehow apply to the challenged testimony of Dr. Marx, Plaintiffs have not made any argument that res judicata would apply to the opinions challenged by Defendant.

Zometa®, and (3) recommending that patients treated with Aredia® and Zometa® receive pre-treatment preventative dentistry to reduce the incidence of ONJ.

The MDL Court ruled, that for the purposes of deciding summary judgment, Dr. Skubitz's testimony regarding a general causation connection between Aredia® and Zometa® and osteonecrosis of the jaw and the adequacy of Defendant's warnings about that connection should be admitted pursuant to Federal Rule of Evidence 702. (*Id.*). The MDL Court declined to rule on whether Dr. Skubitz's opinions regarding extending the dosing interval for patients treated with Zometa® or recommending that patients treated with Aredia® and/or Zometa® receive pre-treatment preventative dentistry to reduce the incidence of ONJ should be precluded under Rule 702. (*Id.*).

Defendant argues that Dr. Skubitz's opinion that reduced dosing may be efficacious should be precluded because his belief that reduced dosing may be efficacious is supported by nothing except one study, which is not scientifically-reliable evidence because it retrospectively reviews a single institution's records without a control group and it is unclear whether ONJ cases described in the study meet Dr. Skubitz's definition of ONJ and is not scientifically reliable evidence on dosing in the multiple myeloma population.

Defendant next argues that Dr. Skubitz's opinion that the implementation of stronger warnings and preventative measures has reduced the incidence of ONJ is not relevant because it does not fit the facts of Mr. D'Agnese's case. Defendant argues that any claim that Mr. D'Agnese would have avoided his alleged ONJ if he had undergone a comprehensive dental exam prior to undergoing bisphosphonate therapy is belied by the fact that, prior to initiating Zometa® therapy, Dr. Olshan performed a detailed examination of Mr. D'Agnese's oral cavity and, from that examination, Dr. Olshan determined that there was no need for Mr. D'Agnese to undergo an invasive surgery. Defendant argues that Dr. Mansfield testified that a warning regarding a pre-prescription dental exam is irrelevant in Mr. D'Agnese's case given Dr. Olshan's examination. Defendant further argues that this opinion should be excluded because Dr. Skubitz offers

no scientifically reliable evidence to support it.

Defendant next argues that Dr. Skubitz's opinions about labels are not relevant to Mr. D'Agnese's case because Dr. Skubitz testified that he would not offer any opinions at trial suggesting that Defendant should have communicated information on ONJ to prescribing physicians prior to September 2003. Defendant argues that this does not apply to Mr. D'Agnese taking the drugs between 1998 and 2005.

Defendant next argues that Dr. Skubitz should not be permitted to testify regarding osteopetrosis, pycnodysostosis, or phossy jaw because he testified that he would not opine that osteopetrosis and pycnodysotosis should have alerted Defendant to the alleged association between Zometa® and ONJ. With regard to this category, the Court cannot exclude testimony that Dr. Skubitz does not intend to offer and, thus, Defendant's request for a *Daubert* hearing on this testimony is denied without prejudice to Defendant making any appropriate objections to such testimony at trial.

Defendant next argues that Dr. Skubitz should not be permitted to offer the opinion that Aredia® and Zometa® labels should have included information regarding the incidence rate of ONJ because (1) he cannot say when he believes a five percent rate should have appeared on labels, (2) he conceded he would not opine that either the 2003 Aredia® or Zometa® labels or the March 2004 labels should have included information regarding the incidence of ONJ, and (3) he admitted that the only randomized controlled studies studying the incidence of ONJ in Zometa® users demonstrated a rate of about one percent.

Defendant next argues that Dr. Skubitz lacks any qualifications or expertise on FDA labeling and should not be permitted to opine on the adequacy of the labeling or Defendant's participation with the FDA regarding the labels.

Defendant next argues that Dr. Skubitz should not be permitted to offer opinions on general causation. The MDL Court has already considered this issue and ruled that such testimony is admissible when it stated that, Dr. Skubitz's testimony regarding a general causation connection between Aredia® and Zometa® and osteonecrosis of the

jaw and the adequacy of Defendant's warnings about that connection should be admitted pursuant to Federal Rule of Evidence 702. Defendant has failed to present any evidence to the Court that the MDL Court did not consider the challenges Defendant now makes, or, if the MDL Court did not consider those challenges, the reasons Defendant did not make such challenges in its earlier motion. These challenges do not appear to be specific to Mr. D'Agnese's case, but rather appear to challenge Dr. Skubitz's case wide testimony regarding the causal connection between bisphosphonates and ONJ. Accordingly, Defendant has presented no convincing reason for this Court to reconsider the MDL Court's decision regarding the admissibility of Dr. Skubitz's testimony regarding the general causation connection between Aredia® and Zometa® and osteonecrosis of the jaw and the adequacy of Defendant's warnings about that connection and, thus, that testimony should be admitted pursuant to Federal Rule of Evidence 702.

With regard to the other challenged portions of Dr. Skubitz's testimony, Plaintiffs argue that other courts in other districts have ruled on *Daubert* motions in other cases that were part of the MDL and have admitted at least some of the testimony challenged by Defendant in the motions before this Court.[7] Plaintiffs do not make any arguments in response to Defendant's challenges to Dr. Skubitz's testimony nor do they explain why Dr. Skubitz's testimony should be admitted under Federal Rule of Evidence 702.

Accordingly, Defendant has raised material disputes as to the admissibility of the challenged testimony of Dr. Skubitz, with the exception of the challenged testimony concerning osteopetrosis, pycnodysostosis, or phossy jaw and general causation connection between Aredia® and Zometa® and osteonecrosis of the jaw and the adequacy of Defendant's warnings, and, thus, the Court must hold a *Daubert* hearing to determine if Dr. Skubitz's opinions on the matters challenged by Defendant are

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[7] Although the Court gave Plaintiffs the opportunity to explain whether or not res judicata would somehow apply to the challenged testimony of Dr. Skubitz, Plaintiffs have not made any argument that res judicata would apply to the opinions challenged by Defendant.

admissible under Federal Rule of Evidence 702. If Plaintiffs do not intend to offer the remaining *challenged* testimony of Dr. Skubitz, Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Skubitz's testimony will be vacated, Dr. Skubitz will not be permitted to testify on the challenged subjects at trial, and the *Daubert* motion will be denied as moot.

F. Defendant's Daubert Motion to Exclude Testimony of Dr. Wayne Ray (Doc. 90)

Dr. Ray is a statistics/epidemiology professor, who Plaintiffs have retained to give the opinion that Aredia® and Zometa® cause ONJ. Defendant seeks to preclude Dr. Ray's testimony in its entirety pursuant to *Daubert* and Rule 702 because Dr. Ray used an unreliable, untested, and non-peer-reviewed methodology.

Plaintiffs argue that other courts in other districts have ruled on *Daubert* motions in other cases that were part of the MDL and have admitted at least some of the testimony challenged by Defendant in the motions before this Court.[8] Plaintiffs do not make any arguments in response to Defendant's challenges to Dr. Ray's testimony nor do they explain why Dr. Ray's testimony should be admitted under Federal Rule of Evidence 702.

Accordingly, Defendant has raised material disputes as to the admissibility of Dr. Ray's testimony and, thus, the Court must hold a *Daubert* hearing to determine if Dr. Ray's opinions are admissible under Federal Rule of Evidence 702. If Plaintiffs do not intend to offer testimony of Dr. Ray, Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Ray's testimony will be vacated, Dr. Ray will not be

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[8] Although the Court gave Plaintiffs the opportunity to explain whether or not res judicata would somehow apply to the challenged testimony of Dr. Ray, Plaintiffs have not made any argument that res judicata would apply to the opinions challenged by Defendant.

permitted to testify at trial, and the *Daubert* motion will be denied as moot.

G. Defendant's Daubert Motion to Exclude Testimony of Dr. Parisian (Doc. 89)

Dr. Parisian is an FDA regulatory expert. Defendant argues that Dr. Parisian seeks to testify (1) that Defendant has violated FDA statutes, regulations, guidance documents and industry standards, and (2) about Defendant's corporate conduct, knowledge, and communications regarding Aredia® and Zometa® between Defendant and the FDA and physicians. Defendant argues that Dr. Parisian's testimony is inadmissible under *Daubert* and Rule 702 because (1) she is unqualified to opine abut NPC's compliance with drug regulations because her experience at the FDA was solely in the device division; (2) her opinions that NPC violated various drug regulations or pharmaceutical industry standards are improper legal conclusions; (3) her personal interpretations and regurgitation of corporate documents invades the province of the jury and exceeds the scope of proper expert testimony, (4) her speculation about NPC's intent and state of mind is improper; (5) her testimony about NPC's labeling regarding Aredia® and Zometa® is irrelevant given the particular facts of this case and (6) she tries to give causation testimony, though she admits that she is unqualified to do so.

In Response, Plaintiffs argue that Defendant has failed to identify the opinions that Dr. Parisian seeks to give in this case, because, although Defendant purports to inform the Court what those opinions are, it has not put those opinions in the Record. Indeed, in its Motion to Exclude Dr. Parisian's testimony, Defendant cites to a Report that was lodged and attached to a Motion to Seal. However, this Court denied the Motion to Seal and, thus, the Report was never filed. This Court cannot rely on documents that are not in the Record and cannot rely on Defendant's regurgitation of Dr. Parisian's opinions to determine if Dr. Parisian's actual opinions, *in this case*, are admissible under *Daubert* or Federal Rule of Evidence 702.

Accordingly, Defendant has failed to show that there is a material dispute as to the admissibility of Dr. Parisian's opinions and the request for a *Daubert* hearing and Motion

to Exclude Dr. Parisian's testimony is denied without prejudice to Defendant making appropriate objections at trial.

H. Defendant's Daubert Motion to Exclude Testimony of Dr. Fletcher (Doc. 91)

Although the *Daubert* Motion regarding the exclusion of testimony of Dr. Fletcher has been fully briefed, in their supplement to the Court, Plaintiffs state that "Dr. Fletcher is withdrawn and is moot." (Doc. 137 at 3). Because Plaintiffs do not intend to offer any testimony of Dr. Fletcher, Defendant's Motion to Exclude Dr. Fletcher's testimony is denied as moot.

IV. CONCLUSION

Based on the foregoing,

IT IS ORDERED that Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83) is granted in part and denied in part as follows:

Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83) is granted to the extent it seeks to exclude Dr. Green's opinion that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ. With regard to Dr. Green, the Motion is denied in all other respects without prejudice to Defendant making appropriate objections at trial.

Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83) is denied as to the challenges to Dr. Lines' opinions without prejudice to Defendant making appropriate objections at trial.

Defendant's Daubert Motion to Exclude Testimony of Plaintiffs' Non-Retained Experts (Doc. 83) is granted to the extent that it seeks to exclude Dr. Marischen's opinion that he had no reason to disagree with the opinion that Zometa® caused Mr. D'Agnese's ONJ and is denied in all other respects without prejudice to Defendant making appropriate objections at trial.

IT IS FURTHER ORDERED that Defendant's Daubert Motion to Exclude

Testimony of Dr. Mansfield (Doc. 84) is denied.

IT IS FURTHER ORDERED that the Court will hold a *Daubert* hearing on Defendant's Daubert Motion to Exclude Testimony of Dr. Vogel (Doc. 85). Such hearing will be limited solely to the challenges made in that Motion. Namely, Dr. Vogel's testimony regarding (1) the adequacy of Defendant's drug labeling; (2) opinions that Defendant misrepresented causation evidence, attempted to misdirect the focus of medical attention away from the jaw area by referencing corticosteroids, minimized the incidence rate of ONJ, knew and failed to communicate that ONJ occurs in patients after fewer infusions of Zometa® than Aredia®, knew and failed to communicate that a decrease in the duration, dose, and/or frequency of therapy decreases the incidence of ONJ; (3) whether Dr. Vogel's opinions regarding preventive dental measures fit the facts of Mr. D'Agnese's case; (4) that the incidence rate of ONJ in patients on Aredia® and Zometa® is generally five percent; (5) that a reduced dosing schedule has shown equal efficacy and less risk and that Defendant improperly failed to disseminate information about alternative dosing schedules, and (6) that BPs are more likely to accumulate in the jaw than in other bones due to higher remodeling rates and higher uptake of bisphosphonates.

If Plaintiffs do not intend to offer the *challenged* testimony of Dr. Vogel, **IT IS ORDERED** that Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Vogel's testimony will be vacated, Dr. Vogel will not be permitted to testify on the challenged subjects at trial, and the *Daubert* motion will be denied as moot.

IT IS FURTHER ORDERED that Defendant's Motion to Exclude the Testimony of Dr. Marx (Doc. 87) is denied in part as follows:

Defendant's Motion to Exclude the Testimony of Dr. Marx (Doc. 87) is denied to the extent it seeks to preclude Dr. Marx's general causation opinions and Dr. Marx's opinions about the biological mechanism by which BP drugs allegedly cause ONJ.

IT IS ORDERED that the Court will hold a *Daubert* hearing on the remainder of

Defendant's Motion to Exclude the Testimony of Dr. Marx (Doc. 87) as follows:

Such hearing will be limited to the following portions of Dr. Marx's testimony (1) whether Dr. Marx's opinions regarding the adequacy of Defendant's warnings fit the facts of Mr. D'Agnese's case; (2) whether Dr. Marx's opinions regarding preventative dental measures fit the facts of Mr. D'Agnese's case; (3) Dr. Marx's opinion that Defendant ignored evidence that bisphosphonates caused ONJ and, thus, acted in bad faith; (4) Dr. Marx's opinion that NPC's clinical trials were a serious deviation of proper research data recording and jaw and mouth examinations were not routinely performed as part of the trial; and (5) Dr. Marx's opinion that five patients in the clinical trials had bisphosphonate-related ONJ.

If Plaintiffs do not intend to offer the remaining challenged testimony of Dr. Marx, **IT IS ORDERED** that Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Marx's testimony will be vacated, Dr. Marx will not be permitted to testify on the remaining challenged subjects at trial, and the *Daubert* motion will be denied as moot.

IT IS FURTHER ORDERED that Defendant's Motion to Exclude the Testimony of Dr. Skubitz (Doc. 88) is denied in part as follows:

Defendant's Motion to Exclude the Testimony of Dr. Skubitz (Doc. 88) is denied to the extent it seeks to preclude Dr. Skubitz's general causation opinions and denied to the extent it seeks to preclude testimony not offered by Dr. Skubitz.

IT IS ORDERED that the Court will hold a *Daubert* hearing on the remainder of Defendant's Motion to Exclude the Testimony of Dr. Skubitz (Doc. 88) as follows:

Such hearing will be limited to the following portions of Dr. Skubitz's testimony: (1) Dr. Skubitz's opinion that reduced dosing may be efficacious; (2) whether Dr. Skubitz's opinion that the implementation of stronger warnings and preventative measures has reduced the incidence of ONJ fits the facts of Mr. D'Agnese's case; (3) Dr. Skubitz's opinion that Aredia® and Zometa® labels should have included information

regarding the incidence rate of ONJ; and (4) Dr. Skubitz's opinions regarding the adequacy of labeling or Defendant's participation with the FDA regarding labels.

If Plaintiffs do not intend to offer the remaining challenged testimony of Dr. Skubitz, **IT IS ORDERED** that Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Skubitz's testimony will be vacated, Dr. Skubitz will not be permitted to testify on the remaining challenged subjects at trial, and the *Daubert* motion will be denied as moot.

IT IS FURTHER ORDERED that Defendant's Daubert Motion to Exclude the Testimony of Dr. Parisian (Doc. 89) is denied without prejudice to Defendant making appropriate objections at trial.

IT IS FURTHER ORDERED that the Court will hold a *Daubert* hearing on Defendant's Daubert Motion to Exclude the Testimony of Wayne Ray (Doc. 90).

If Plaintiffs do not intend to offer the testimony of Dr. Ray, **IT IS ORDERED** that Plaintiffs shall file a notice with the Court stating that such challenged testimony is not offered within 5 days of the date of this Order and the *Daubert* hearing regarding Dr. Ray's testimony will be vacated, Dr. Ray will not be permitted to testify at trial, and the *Daubert* motion will be denied as moot.

IT IS FURTHER ORDERED that Defendant's Daubert Motion to Exclude the Testimony of Dr. Fletcher (Doc. 91) is denied as moot.

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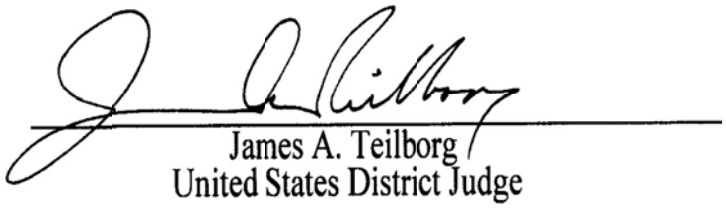
IT IS FINALLY ORDERED setting a *Daubert* hearing on Defendant's Daubert Motion to Exclude Testimony of Dr. Vogel (Doc. 85), Defendant's Motion to Exclude the Testimony of Dr. Marx (Doc. 87), Defendant's Motion to Exclude the Testimony of Dr. Skubitz (Doc. 88), and Defendant's Daubert Motion to Exclude the Testimony of Wayne Ray (Doc. 90) for Thursday, February 14, 2013 at 9:00 a.m. at 401 W. Washington Street, in Courtroom 503, in Phoenix, Arizona.

Dated this 28th day of January, 2013.



James A. Teilborg
United States District Judge