UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Candice Kruszka and Alan Kruszka,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation,

Defendant.

Civil No. 07-2793 (DWF/JJK)

MEMORANDUM OPINION AND ORDER

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INTRODUCTION

This matter is before the Court on the following motions: (1) Plaintiffs Candice Kruszka's ("Kruszka") and her husband Alan Kruszka's ("Mr. Kruszka") (collectively, "Plaintiffs") Motion *In Limine* to Exclude Testimony of Duplicative Defense Experts against Defendant Novartis Pharmaceuticals Corporation ("Novartis" or "Defendant") (Doc. No. 43); (2) Plaintiffs' Motion to Exclude Expert Testimony of Dr. Carol Ann Huff (Doc. No. 72); (3) Plaintiffs' Motion to Exclude Testimony of Dr. Dale A. Baur (Doc.

No. 81); (4) Plaintiffs' Motion to Exclude Expert Testimony Relating to Alleged FDA Compliance and/or Novartis's "State of Mind" (Doc. No. 97); (5) Plaintiffs' Motion to Unseal the Second Declaration of Robert G. Germany and Exhibits 1-182 (Doc. No. 109); (6) Defendant's Motion to Exclude Expert Testimony of Dr. Suzanne Parisian (Doc. No. 46); (7) Defendant's Motion to Exclude Testimony of Plaintiffs' Expert Dr. Keith Skubitz (Doc. No. 54); (8) Defendant's Motion to Exclude Expert Testimony of Plaintiffs' Expert Professor Wayne Ray (Doc. No. 56); and (9) Defendant's Motion to Exclude Expert Testimony of Dr. James Vogel (Doc. No. 79). For the reasons set forth below, the Court grants in part and denies in part the motions.

BACKGROUND

The facts of this case have been fully set forth in the Court's May 19, 2014 Amended Memorandum Opinion and Order addressing summary judgment and two *Daubert* motions ("May 2014 Order"). (Doc. No. 202 at 2-9.) Thus, the Court briefly summarizes the facts of this case as follows: This case relates to claims that Kruszka suffered osteonecrosis of the jaw ("ONJ")—also known as dead jaw bone—as a result of using Novartis's product Aredia® ("Aredia"). Aredia is a bisphosphonate drug that is used to treat multiple myeloma, a form of blood cancer from which Kruszka suffered. Plaintiffs refer to Kruszka's ONJ as bisphosphonate-induced osteonecrosis of the jaw ("BIONJ").[1]

[1] BONJ, BRONJ, BIONJ, and BON are similar acronyms that have all been used to describe ONJ seen in bisphosphonate users. The Court will use BRONJ and BIONJ interchangeably. (See Doc. No. 75 at 3 n.1.)

In the May 2014 Order, the Court granted in part and denied in part Defendant's motion for summary judgment. The Court also allowed at least some testimony from Plaintiffs' case-specific retained and non-retained expert witnesses Drs. Gertz, Juhlin, and Kraut, and also from Plaintiffs' expert Dr. Marx. Both parties now seek to exclude the expert testimony of a number of additional potential expert witnesses under *Daubert* and the relevant Federal Rules of Evidence. Plaintiffs additionally seek the unsealing of certain exhibits and a corresponding declaration and have also moved *in limine* to exclude the testimony of duplicative defense experts.

DISCUSSION

I. *Daubert* Motions

A. Legal Standard

Before accepting the testimony of an expert witness, the trial court is charged with a "gatekeeper" function of determining whether an opinion is based on sound, reliable theory, or whether it constitutes rank speculation. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993). In *Daubert*, the United States Supreme Court imposed an obligation on trial court judges to ensure that scientific testimony is not only relevant, but also reliable under the Federal Rules of Evidence. *Id*. at 579.

Proposed expert testimony must meet three prerequisites to be admissible under Federal Rule of Evidence 702. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). "First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact." *Id.* "[I]t is the responsibility of the trial judge to determine whether a particular expert has sufficient

specialized knowledge to assist jurors in deciding the specific issues in the case." *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001). Second, the proposed expert must be qualified. *Lauzon*, 270 F.3d at 686. Third, the proposed evidence must be reliable. *Id.* The proponent of the expert testimony bears the burden to prove its admissibility by a preponderance of the evidence. *Daubert*, 509 U.S. at 592 n.10.

In determining whether the proposed expert testimony is reliable, the Court considers: (1) whether the theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known rate of potential error; and (4) whether the theory has been generally accepted. *Id.* at 593-94. The purpose of these requirements "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

In *Kumho Tire*, the Supreme Court concluded that "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.* In other words, "a trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony." *Id.* "The objective of that requirement is to ensure the reliability and relevance of expert testimony." *Id.*

The Court's focus should be on whether the testimony is grounded in scientifically valid reasoning or methodology. *United States v. Dico, Inc.*, 266 F.3d 864, 869 (8th Cir.

2001). "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (internal citation omitted).

B. Plaintiffs' Motion to Exclude Expert Testimony of Dr. Carol Ann Huff

1. Background

Dr. Carol Ann Huff ("Dr. Huff") is an oncologist who is certified in internal medicine and oncology. (Doc. No. 150 ("Huff Exs. Index") ¶ 1, Ex. 1 ("Huff Report").) She is a faculty member at Johns Hopkins University where she began working in 1997 and where she has been in the Department of Oncology as an Associate Professor of Medicine and Director of the Department's multiple myeloma program since 2001. (*Id*.) She is a member of a number of cancer-related associations and committees. (*Id*.) Dr. Huff has worked with a number of multiple myeloma patients over the years. (*Id*.) Dr. Huff is involved in clinic research in the multiple myeloma field and has authored or co-authored several book chapters, as well as more than twenty peer-reviewed scientific articles and eighteen abstracts. (*Id*.) Novartis proffers Dr. Huff to opine on issues relating to myeloma and its treatment, including the effects of its treatments and therapies. In part, Dr. Huff's expert report opines that osteomyelitis cannot be ruled out as a cause of Kruszka's jaw problems, and that Kruszka benefitted from her Aredia therapy.

2. Analysis

Plaintiffs seek to exclude Dr. Huff's specific causation testimony. Plaintiffs make two main arguments. First, Plaintiffs argue that Dr. Huff is unqualified to render the opinions she proffers, particularly any opinion regarding the specific cause of Kruszka's jaw problems, because she is an oncologist and is not an oral maxillofacial surgeon or dentist who works with osteomyelitis or ONJ. Second, Plaintiffs argue that Dr. Huff cannot proffer opinions on quality-of-life improvements and special benefits associated with Aredia. Separately, Plaintiff seeks to exclude Dr. Huff's declaration that Novartis included as an attachment to its opposition to Plaintiffs' *Daubert* motion on Dr. Huff ("Huff Decl."). The Court addresses each issue below.

As an initial matter, the Court concludes that Dr. Huff is qualified to opine on myeloma treatment and therapies and their impact. A medical doctor need not have treated the specific disease at issue to opine on medical matters relating to that condition. *Dittrich-Bigley v. Gen-Probe, Inc.*, Civil No. 11-17-62, 2013 WL 3974107, at *7 (D. Minn. July 31, 2013) (finding that despite not being an expert on treating osteomyelitis specifically, a pediatrician was sufficiently qualified to opine on the cause of an infant's osteomyelitis). Dr. Huff is highly qualified as an oncologist and can therefore opine on issues relating to her oncological work, including treating myeloma, prescribing Aredia and Zometa®[2] ("Zometa") to treat myeloma, the immunosuppressive effect of myeloma-related treatments, and the specific effects of Aredia treatment. This

[2] Zometa is also a bisphosphonate used to treat cancer patients and is manufactured by Novartis. Kruszka did not receive Zometa.

also includes opining on Kruszka's clinical course of treatment. Dr. Huff regularly treats the cancer at issue here through a number of different methods and therapies, one of which is by regularly prescribing Aredia and Zometa. Dr. Huff has also written on and reviewed the key medical literature relating to complications associated with myeloma and its therapies.

Additionally, because Dr. Huff is qualified to opine on cancer treatments, particularly treatments with Aredia, she is similarly qualified to address issues of improved quality of life for patients, as well as the benefits of such therapies. To the extent that her opinions on Kruszka are grounded in her expertise with respect to myeloma treatments and therapies, she can also opine on Kruszka specifically. Dr. Huff need not have treated Kruszka to apply her expertise to Kruszka's medical records. Dr. Huff bases her opinions regarding quality of life on peer-reviewed literature that this Court determines to be of sufficient reliability. (*See* Huff Report.) Her opinions are also supported by reliable clinical trials and her own clinical practice experience. (*See id*.)

Dr. Huff, however, cannot opine on the diagnosis of osteomyelitis or ONJ, or issues relating to dental training. Her expertise reaches the effects of bisphosphonate treatments and other treatments, but this is separate from addressing the cause of Kruszka's jaw conditions. Thus, the Court limits Dr. Huff's specific causation testimony as the court did in *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420 (E.D.N.Y. 2011). In that case, the court held that the specific causation expert could appropriately address the existence of alternative risk factors, and whether those factors indicate that a "particular opinion on causation cannot be determined," not what caused the patient's

specific jaw problems. *Deutsch*, 768 F. Supp. 2d at 483-84. Put another way, Dr. Huff's testimony can include opinions rebutting specific causation testimony so long as it is tied to her work and expertise as an oncologist who treats and also conducts research relating to myeloma patients. *See id*.

The strength and accuracy of Dr. Huff's opinions with respect to issues arising from and related to myeloma therapies are appropriately tested through cross-examination. The Court agrees with Novartis that Dr. Huff's testimony is not rendered unreliable simply because another doctor may testify to different possible causes. This is a matter that goes to credibility and not admissibility. *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 569 (8th Cir. 1988) ("The relative skill or knowledge of an expert goes to the weight of that witness's testimony, not its admissibility."). Similarly, the bulk of Plaintiffs' arguments for the exclusion of Dr. Huff's testimony, for example those relating to whether immunosuppression is meaningful in this context, whether Aredia is in fact beneficial, and whether the benefits are to be considered in composite rather than independently, all go to credibility and weight.

With respect to the Huff Declaration, the Court agrees with Plaintiffs that it is not properly before the Court. The Huff Declaration includes information not contained in the Huff Report. Any such additional expert information must come before the Court in the form of a supplemental or rebuttal expert report and is therefore improper and untimely as currently filed. If the opinions Dr. Huff offers are beyond the scope of her expert report, they are inadmissible as beyond the scope of Rule 26. The Court, however,

notes that the existence of the Huff Declaration does not impact its decision above as to the admissibility of Dr. Huff's testimony.

C. Plaintiffs' Motion to Exclude Testimony of Dr. Dale A. Baur

1. Background

Dr. Dale A. Baur ("Dr. Baur") is a licensed dentist and board-certified oral and maxillofacial surgeon. (Doc. No. 50 ("Odette Aff. on Duplicative Experts") ¶ 3, Ex. 1 ("Baur Report") at 1.) Dr. Baur received his dental degree in 1980, completed his residency in oral and maxillofacial surgery in 1997, and completed a fellowship in 2001. (*Id.*) He is currently an Associate Professor and Chair of the Department of Oral and Maxillofacial Surgery at Case Western Reserve University. (*Id.*) Dr. Baur is also the Division Chief of Oral and Maxillofacial Surgery at University Hospitals/Case Medical Center in Cleveland, Ohio. (*Id.*) Dr. Baur is involved in a number of dental societies and has published approximately thirty-two peer-reviewed articles and has authored nine book chapters. (*Id.*) With respect to bisphosphonates and ONJ, he has presented seven times and has presented a case series on the topic of ONJ. (*Id.*) Finally, he has treated cancer and non-cancer patients with ONJ who did not have a history of bisphosphonate use. (*Id.*)

Novartis proffers Dr. Baur to opine on matters relating to his expertise as an oral and maxillofacial surgeon.

2. Analysis

Plaintiffs do not seek to exclude Dr. Baur's testimony in its entirety, but instead seek to exclude Dr. Baur's opinions relating to: (1) whether the benefits of

bisphosphonate therapy outweigh the risks; (2) whether bisphosphonate therapy improves quality of life; and (3) whether the warnings disseminated with Novartis's bisphosphonate drugs were effective, timely, and appropriate (including whether Kruszka would have taken bisphosphonates if warned of its risks (proximate causation)).

Plaintiffs argue that Dr. Baur lacks sufficient qualifications to render the opinions listed and also question the reliability of Dr. Baur's opinions, arguing that they lack an adequate factual and evidentiary basis. Specifically, Plaintiffs argue that because Dr. Baur is not an oncologist and does not prescribe bisphosphonates, he cannot do a risk-benefit analysis of bisphosphonate therapy. Additionally, Plaintiffs argue that Dr. Baur's background, experience, education, and training fail to establish his qualification to opine on bisphosphonate warnings.

Dr. Baur is undoubtedly qualified to opine on ONJ as a dentist and oral and maxillofacial surgeon with decades of experience working with patients with ONJ. Plaintiffs do not dispute this. Dr. Baur is further qualified to opine on questions of causation with respect to bisphosphonates and ONJ based on the presentations he has made on that topic, his case series, and his review and knowledge of relevant scientific literature and other relevant materials. (*See* Baur Report.)

This, however, does not qualify Dr. Baur to opine on bisphosphonates as an independent topic. Dr. Baur presents no evidence that he has any degree of expertise on bisphosphonates outside of their interaction with ONJ—he does not prescribe them, is not an oncologist, and has not spoken on, researched, or written about bisphosphonates specifically. The sole basis of Dr. Baur's knowledge with respect to the risks and

benefits and quality-of-life impact of bisphosphonate therapy, and bisphosphonate labeling[3] appears to be scientific literature. In fact, Novartis admits that Dr. Baur's opinions on these issues are largely based on his review of relevant scientific literature (Doc. No. 155 at 7-9, 12) ("Dr. Baur has considered extensive relevant literature published in the oral and maxillofacial surgery field . . ." and "Dr. Baur considered this abundant medical and dental literature supporting his opinion.") "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Here, the analytical gap is too great. *Id.* The mere reading of others' articles on a treatment that is outside of his expertise, though it may loosely connect to his work, is not enough to qualify Dr. Baur on these subjects. In fact, Dr. Baur's main expertise when it comes to bisphosphonates is arguably patients who have jaw problems, but do *not* use bisphosphonates. (*See* Baur Report.) Thus, Dr. Baur's expertise is related to dental and jaw conditions, not cancer therapies.

Accordingly, Plaintiffs' motion to exclude the limited testimony of Dr. Baur is granted only as it relates to the following opinions: (1) whether the benefits of bisphosphonate therapy outweigh the risks; (2) whether bisphosphonate therapy improves

[3] This extends to testimony relating to whether Kruszka would have taken bisphosphonates even if warned of their risks (proximate causation). Dr. Baur was neither her, nor anyone's, prescribing or myeloma-treating physician.

quality of life; and (3) whether the warnings disseminated with Novartis's bisphosphonate drugs were effective, timely, or appropriate.

D. Plaintiffs' Motion to Exclude Expert Testimony Relating to Alleged FDA Compliance and/or Novartis's "State of Mind"

1. Background

Dr. Janet B. Arrowsmith-Lowe ("Dr. Arrowsmith") is the president of Arrowsmith-Lowe Consulting, Inc. which is a drug, biologic, and device consulting firm. (Doc. No. 50 ("Odette Aff. on Duplicative Experts") ¶ 5, Ex. 3 ("Arrowsmith Report") at ¶ I.) Dr. Arrowsmith received her M.D. in 1972 and completed her residency in 1982. (*Id*.) She is board certified and licensed in internal medicine and is a member of a number of associations and societies. (*Id*.) Dr. Arrowsmith worked at the National Centers for Disease Control and Prevention (the "CDC") from 1984 to 1986 and was assigned to the Food and Drug Administration (the "FDA"). (*Id*.) In this role she worked with the CDC and the FDA on epidemiologic investigations of reported adverse drug events, among other things. (*Id*.) As a staff epidemiologist she monitored post-marketing safety of marketed drugs. (*Id*.) As a medical review officer at the FDA, Dr. Arrowsmith reviewed Investigational New Drug ("IND") or Biological Investigational New Drug ("BIND") submissions and New Drug Applications ("NDAs"). (*Id*.) Dr. Arrowsmith has published a number of peer-reviewed medical articles and has co-authored book chapters addressing the FDA's regulations and practices, with a focus on pharmaceutical product safety. (*Id*.)

Dr. David W. Feigal ("Dr. Feigal") is board certified in internal medicine and also has a master's degree in public health relating to epidemiology and biostatistics. (Odette Aff. on Duplicative Experts ¶ 8, Ex. 6 ("Feigal Report") at ¶ I.) Between 1992 and 1994, Dr. Feigal held a number of senior positions at the FDA, including positions at the Center for Drug Evaluation and Research, which is responsible for the review and approval of all new drugs and the ongoing assessment of the quality, safety and effectiveness of marketed drugs. (*Id.*) Dr. Feigal has also served on a number of FDA advisory committees. (*Id*. at 2.) Additionally, Dr. Feigal has held senior positions at various pharmaceutical companies. (*Id*. at 3.)

Novartis generally proffers Drs. Arrowsmith and Feigal to opine on the regulatory framework within which pharmaceutical companies work when bringing new drugs to market, the continued FDA monitoring of those drugs once approved, and the FDA's approval and post-market safety monitoring of Aredia and Zometa.

2. Analysis

Plaintiffs seek to exclude the testimony of certain experts who proffer testimony relating to the FDA regulation of the drugs Aredia and Zometa, and relating to NDAs and clinical trials for Zometa. Plaintiffs have detailed the testimony of these experts as follows:

Arrowsmith:	IND applications with FDA; NDAs with FDA; FDA regulation of Aredia and Zometa; FDA safety surveillance of Aredia and Zometa; timeliness and adequacy of Zometa label changes and warnings; post-marketing experience with ONJ; rebuttal of Dr. Parisian (Plaintiffs' FDA expert).

Feigal:	The New Drug Approval Process; INDs; NDA Review; Post-marketing surveillance; Product labeling; development of Aredia and Zometa; post- marketing experience with ONJ and development of a signal; label changes; rebuttal of Dr. Parisian.

(Doc. No. 99 (citing Arrowsmith Report; Feigal Report).) Plaintiffs argue that Drs. Arrowsmith and Feigal's opinions amount to inadmissible opinions about the FDA and Novartis's state of mind. (Doc. No. 99 at 2.) [4]

Novartis argues that their experts' opinions are not intent or "state of mind" opinions and are therefore admissible. Novartis also argues that their experts' opinions are distinguishable from the "state of mind" testimony presented by Plaintiffs' expert Dr. Parisian (*see* Section E, below).

The Court finds that testimony about the FDA and Novartis's state of mind is not appropriate as expert testimony. Expert testimony on "the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *Deutsch*, 768 F. Supp. 2d at 442 (citing *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004)). Thus, Drs. Arrowsmith and Feigal may not proffer an opinion relating to what individuals at Novartis or with the FDA thought with respect to certain documents or about their motivations.

However, the Court agrees with Novartis that not all of Dr. Arrowsmith's and Dr. Feigal's testimony relating to the FDA seeks to opine on "the intent, motives, or

[4] Plaintiffs initially sought to exclude four experts in this Motion, however, two have been withdrawn (Drs. Bunn and Bukowski). Therefore the Court only addresses Drs. Arrowsmith and Feigal.

states of mind" of Novartis and the FDA. Dr. Feigal has knowledge of the FDA's regulation of prescription drugs and corresponding labeling and also has knowledge about pharmaceutical company post-marketing surveillance programs. Dr. Arrowsmith also has knowledge relating to FDA regulatory issues from her work at the FDA and her consulting work regarding the FDA. Thus, both Drs. Arrowsmith and Feigal have the expertise and experience to allow them to opine on the reasonableness of Novartis's interaction with the FDA and compliance with FDA regulations, including with respect to labeling and warnings, and such testimony would be helpful to the trier of fact from a regulatory perspective. *See, e.g.*, *Deutsch*, 768 F. Supp. 2d at 465-66.

Testimony about the reasonableness of Novartis's actions is different from testimony including opinions about whether Novartis acted as a "good company," which the Court will not allow. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007) ("The question of corporate intent is one for the jury, not for an expert."). For example, should Dr. Arrowsmith seek to testify that Novartis acted "thoroughly and diligently" when it investigated reports or acted "on its own initiative," such testimony is improper state of mind testimony—Drs. Arrowsmith and Feigal cannot know whether or not this was the case from either the perspective of Novartis or the FDA. *In re Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motives of parties or others lie outside the bounds of expert testimony."). Conversely, testimony that Novartis acted in accordance with regulations or established procedure which reflects diligence; or fact-based testimony that the FDA "found no fault with the company conduct"; or testimony that opines on what the FDA or Novartis actually did, rather than

thought, are properly within the scope of admissible testimony. Remaining issues such as Plaintiffs' claim that the FDA never made a finding on adequacy are disputed issues of fact that go to weight and not admissibility and are to be challenged on cross-examination.

Thus, as with Dr. Marx (*see* Doc. No. 202 at 17-180) and Dr. Parisian (below), the Court will not allow Drs. Arrowsmith and Feigal to testify to the state of mind, intent or motives of Novartis or the FDA. To the extent that certain phrases used by Novartis's experts move their opinions into impermissible "state of mind" or other "intent or motive" testimony, the Court shall address specific objections at trial, if necessary. Plaintiff's motion on Novartis's "state of mind" experts is therefore granted in part and denied in part.

E. Defendant's Motion to Exclude Expert Testimony of Dr. Suzanne Parisian

1. Background

Dr. Susanne Parisian, M.D. ("Dr. Parisian") is a Board Certified Anatomic and Clinical Pathologist who also holds a master's degree in biology. (Doc. No. 48-2 ("Def. Parisian Index") ¶ 8, Ex. 8 ("Parisian Report") ¶ 1.) She is the founder of MD Assist, Inc., a regulatory and medical consulting firm specializing in matters involving the regulation of products by the FDA. (*Id.*) She was a Medical Officer in the Office of Health Affairs at the FDA. (*Id.* at ¶ 3.) While working for the FDA, Dr. Parisian was an instructor at the FDA's Staff College and was "sent by the FDA to provide guidance on the FDA's interpretation of Food and Drug laws as they pertain to medical products . . . ."

(*Id*. at ¶ 6, 8.) Since leaving the FDA, Dr. Parisian has written a text about the FDA and participated in a panel of experts the FDA convened to comment on proposed changes to requirements for medical device labeling. (*Id*. at ¶ 1, 12.) In this case and a number of related cases, Dr. Parisian seeks to provide (or has provided) her expert opinion with respect to the regulatory framework and processes of the FDA and Novartis's compliance with both.

2. Analysis

Novartis moves to exclude the testimony of Dr. Parisian in its entirety. Novartis moves to exclude Dr. Parisian's testimony on the basis of Federal Rules of Evidence 401-403, 702, and *Daubert*. Novartis questions Dr. Parisian's expertise in general, and also contends that Dr. Parisian is not qualified to offer opinions regarding Novartis's regulatory compliance or regarding Aredia labels because she is not an expert on the drug. (Doc. No. 48 at 12, 18.)

A number of courts have examined the admissibility of Dr. Parisian's expert opinions. The MDL Court declined to examine the admissibly of Dr. Parisian's testimony because the court found it unnecessary to rely upon her testimony for purposes of summary judgment. (Def. Parisian Index ¶ 1, Ex. 1 (*In re Aredia & Zometa Prods. Liab. Litig.*, Civ. No. 06-MD-1760 (M.D. Tenn. Aug. 13, 2009)).) As a result, each transferee court has independently examined the admissibility of Dr. Parisian's testimony.

Novartis first asks the Court to rely on *Hogan v. Novartis Pharm. Corp.*, Civ. No. 06-260, 2011 WL 1533467 (E.D.N.Y. Apr. 24, 2011), where the court excluded

Dr. Parisian's testimony in its entirety. In that case, Plaintiff brought common law claims that were unrelated to FDA regulations, and therefore the court excluded all testimony and evidence discussing the FDA, including Dr. Parisian's testimony. *Id*. at *2. The court, however, did not examine her qualifications. *See id*. Here, FDA regulations are related to Plaintiffs' claims, and, as a result, Dr. Parisian's testimony will not be excluded as irrelevant.

Novartis next argues that Dr. Parisian fails to demonstrate expertise when called at trial. In previous Aredia and Zometa cases, courts have regularly found Dr. Parisian's testimony to be relevant and reliable under *Daubert* as a general matter. *See, e.g.*, *Lemons v. Novartis Pharm. Corp.*, 849 F. Supp. 2d 608, 613 (W.D.N.C. 2012) (finding Dr. Parisian qualified to testify generally due to her significant experience with the FDA and extensive education); *Forman v. Novartis Pharm. Corp.*, 794 F. Supp. 2d 382, 384 (E.D.N.Y. 2011) ("Dr. Parisian testified . . . by taking this information and applying the relevant FDA regulations and procedures. [T]his is the same methodology that she applied while working at the FDA.").

Specifically, a number of courts have determined that Dr. Parisian is qualified to testify as an expert on issues of the FDA regulatory process. *See, e.g.*, *Guenther v. Novartis Pharm. Co.*, Civ. No. 08-456, 2013 WL 1278089, at *2-3 (M.D. Fla. Mar. 28, 2013) (finding Dr. Parisian generally qualified to testify regarding the FDA regulatory process due to her experience in the field); *Deutsch*, 768 F. Supp. 2d at 464 ("Dr. Parisian is qualified to testify with regard to the FDA . . . [including] regulatory requirements relating to the development, testing, marketing, and post-market surveillance of

prescription drugs.") Beyond this, Dr. Parisian has also frequently been permitted to testify to the extent she explains the FDA regulatory standards themselves. *See, e.g.*, *Lemons*, 849 F. Supp. 2d at 614 ("Dr. Parisian's testimony will assist the trier of fact in understanding the complexity of the FDA's regulatory scheme . . ."); *Deutsch*, 768 F. Supp. 2d at 465 ("[T]he FDA and others in the industry have continued to rely on her for guidance on FDA regulations . . . .")

Dr. Parisian has also been tested and deemed qualified with respect to issues of Novartis's compliance with FDA regulations.[5] For example, the Court in *Forman* found that, "Dr. Parisian's methodology is reliable and [she] is permitted to render opinions on the reasonableness of Novartis' conduct in its interactions with the FDA and compliance with FDA regulations, including Novartis' interactions with the FDA with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials." *Forman*, 794 F. Supp. 2d at 384 (internal citations and quotations omitted). This is distinguishable, however, from any testimony from the perspective of Novartis or the pharmaceuticals industry as Dr. Parisian has not had experience and does not have expertise from this point of view. *See Deutsch*, 768 F. Supp. 2d at 468 (excluding Dr. Parisian's testimony regarding what a "reasonable manufacturer would do" and "industry standards" because she "has never worked at a pharmaceutical company or with a pharmaceutical company outside of her interactions with companies involved in FDA processes.").

[5] Novartis argues that Dr. Parisian has stated that Novartis never deviated from any regulations she cites in her reports. (Doc. No. 48 at 7.) This goes to the weight of Dr. Parisian's testimony on this issue, not its admissibility.

The Court agrees with the findings of the courts detailed above, and it too finds that Dr. Parisian is qualified with respect to FDA regulations, processes, and Novartis's actions as they relate to those subjects. As a general matter, Dr. Parisian is a credible and reliable expert in her particular field. Dr. Parisian has extensive knowledge of the FDA's processes through her work with the FDA, supported by her appointment as an instructor. She has continued to supplement her knowledge since leaving the FDA through her work with MD Assist and with the expert panel. Novartis's argument that because Dr. Parisian has not worked with live patients for more than twenty years, and worked at the FDA for only 4 years, she is therefore unqualified to opine on matters of FDA regulations, does not alter the Court's conclusion. Such testimony goes to the weight of her testimony, not the admissibility.

As such, the Court concludes that Dr. Parisian is qualified to testify on matters related to FDA regulation outlined above and her testimony is sufficiently based on specialized knowledge which will be helpful for the jury to understand the complex topic of FDA regulation. (*See* Def. Parisian Index ¶ 28, Ex. 28 (*Stevens v. Novartis Pharm. Corp.*, Civil No. DV-08-100, at 5 (Mont. 4th Jud. Dist. Ct., Oct. 14, 2009)).) Of course, attempts by Dr. Parisian to offer an opinion as to whether Novartis violated the law with respect to the FDA constitute a legal conclusion and are not admissible. Thus, in sum, Novartis's motion to exclude the entirety of Dr. Parisian's testimony is denied, and Dr. Parisian is permitted to testify on the FDA regulatory process and regulations and on Novartis's compliance. Also, Dr. Parisian will be permitted to testify regarding

Novartis's conduct in its interactions with the FDA regarding labels and warnings on prescription drugs, but only from the perspective of her knowledge about the FDA.

However, as have numerous other courts in related cases, the Court also limits Dr. Parisian's testimony. A number of courts have found that Dr. Parisian is not qualified to testify regarding causation, monitoring clinical trials, corporate state of mind, ghostwriting, industry standards outside FDA regulations, or to make legal conclusions. *See, e.g.*, *Guenther*, 2013 WL 1278089, at *2-3; *see also Chiles v. Novartis Pharm. Corp.*, 923 F. Supp. 2d 1330, 1333 (M.D. Fla. 2013).

Here, Plaintiffs agree that Dr. Parisian will not testify regarding medical causation, corporate state of mind, industry standards, monitoring clinical trials, and ghostwriting.[6] (*See* Doc. No. 142 at 8.) Any testimony on these issues is not admissible. However, though Plaintiffs have agreed they will not present any testimony on these issues, the Court briefly outlines certain specific limits on any such testimony as follows.

First, with respect to questions of medical causation that address the direct causal link between bisphosphonates and ONJ, the Court finds that Dr. Parisian is neither an expert on ONJ nor on bisphosphonate medications and may not offer testimony on either issue. (*See* Def. Parisian Index ¶ 11, Ex. 11 at 11.) For example, Dr. Parisian states in her report that "causation is clear," meaning that bisphosphonates clearly cause ONJ.

[6] Dr. Parisian may refer to the Gotcher and Jee article relating to the "rice rat" study. Novartis argues that Dr. Parisian uses this to offer "backdoor causation" opinions. (Doc. No. 142 at 15.) However, the Court has concluded that Dr. Parisian cannot opine on causation, thus the admissibility of this article will depend on the way the evidence is introduced and whether the proper foundation is laid. The Court will address these issues in accordance with Federal Rule of Evidence 104 and Article 7, including specifically Rule 703.

Any testimony of this nature will not be permitted. (Parisian Report at ¶ 15.) Further, Dr. Parisian will also not be permitted to opine that Novartis should have conducted safety evaluations sooner, or that Novartis should have noticed the link between bisphosphonates and ONJ sooner. *Id*.

Second, as Novartis asserts, regulatory causation or "causal association" is also outside Dr. Parisian's expertise and should be excluded. Under 21 C.F.R. § 201.57(c)(6)(i), which relates to labeling requirements for prescription drugs, "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established . . . ." Plaintiffs' counsel fails to meaningfully distinguish the causal association outlined in § 201.57(c)(6)(i) from medical causation, and as such, testimony on this issue must be excluded. *See Dopson-Troutt v. Novartis Pharm. Corp.*, Civ. No. 06-1708, 2013 WL 1344755, at *3 (M.D. Fla. Apr. 2, 2013); *Taylor v. Novartis Pharm. Co.*, Civ. No. 06-61337, 2013 WL 5118945, at *9 (S.D. Fla. Apr. 22, 2013). Dr. Parisian's discussion of regulatory causation would not be beneficial to the jury's decision-making process, and is thus not permissible. (*See, e.g.*, Def. Parisian Index ¶ 3, Ex. 3 (*Georges v. Novartis Pharm. Corp.*, Civ. No. 06-5207, at 20 (C.D. Cal. Nov. 2, 2012)) ("Dr. Parisian's attempt to draw this distinction is confusing at best and would almost certainly confuse or mislead the jury.").

Third, to the extent Dr. Parisian attempts to opine on whether Novartis acted according to the regular practices of pharmaceutical companies outside of FDA regulations, Dr. Parisian is not qualified and any such testimony would be unreliable.

Dr. Parisian is an expert on the FDA, not on the industry practices of pharmaceutical companies, and as such she is prohibited from testifying as to whether Novartis complied with industry standards. (*See* Def. Parisian Index ¶ 3, Ex. 3 (*Georges*, Civ. No. 06-5207, at 20 (C.D. Cal. Nov. 2, 2012)).) This does not include testimony as outlined above that strictly pertains to the FDA. For example, Dr. Parisian may discuss Novartis's compliance with 21 C.F.R. § 314.80 as it pertains to Aredia risk information, as that is her field of expertise, but she cannot go outside those boundaries.

Finally, Dr. Parisian's opinions that Novartis convinced doctors to write publications favoring Aredia and Zometa under the guise of independent reporting, or "ghostwriting," are outside the realm of Dr. Parisian's expertise, and, as a result, this category of testimony will not be permitted. (*See* Parisian Report at ¶ 232.) Further, Dr. Parisian may not testify regarding any type of implied coercion of doctors by Novartis to prescribe Novartis drugs as she does in her report. (*Id.* at ¶ 241.) Dr. Parisian may testify as to whether Novartis's marketing complied with FDA regulations, as that is within her area of expertise, but she will not be permitted to expand the discussion beyond those bounds as she has in the past.

In sum, the Court finds that Dr. Parisian is qualified and reliable as an expert on issues relating to FDA processes and regulations and Novartis's compliance therewith. However, Dr. Parisian is precluded from opining on those issues the parties themselves identified as excluded. Also, given the more-than-sufficient pleadings before the Court and the number of cases that have already examined the admissibility of Dr. Parisian's opinions, the Court declines to order a *Daubert* hearing on Dr. Parisian. As a result, the

Court grants in part and denies in part Novartis's motion relating to Dr. Parisian consistent with its analysis above.

F. Defendant's Motion to Exclude Testimony of Plaintiffs' Expert Dr. Keith Skubitz and of Plaintiffs' Expert Professor Wayne Ray

Plaintiff has withdrawn Dr. Keith Skubitz and Professor Wayne Ray as experts. (6/10/14 Hearing Tr. at 98.) Accordingly, the Court dismisses these motions as moot.

G. Defendant's Motion to Exclude Expert Testimony of Dr. James Vogel

1. Background

Dr. James Vogel ("Dr. Vogel") is an oncologist and a hematologist. (Doc. No. 85-2 ("Def. Ex. Index") ¶ 6, Ex. 6 ("Vogel Report") at ¶ 1.) He has been practicing in that field for 35 years. (*Id.*) Dr. Vogel is currently an associate professor at Mount Sinai School of Medicine in the Division of Hematology/Medical Oncology. (Vogel Report at ¶ 12.) Dr. Vogel testified that he has observed ONJ in two patients, though he has treated hundreds with Aredia and Zometa. (Vogel Report at ¶ 16; Def. Ex. Index ¶ 3, Ex. 3 ("Vogel Dep. I") at 126; Def. Ex. Index ¶ 7, Ex. 7 ("Vogel Dep. II") at 17-18.) Dr. Vogel prescribes bisphosphonates in his practice. (Vogel Report at ¶ 15.)

2. Analysis

Novartis seeks to exclude Dr. Vogel's opinions relating to the following: (1) Novartis's corporate conduct; (2) pre-bisphosphonate-treatment dental screening; (3) ONJ incidence; (4) an alternative bisphosphonate dosing-duration regimen that has not been approved by the FDA; and (5) the biological mechanism by which bisphosphonates allegedly affect jaw bones. Novartis is not challenging Dr. Vogel's

general causation opinion that Aredia can cause ONJ. Novartis is also not challenging Dr. Vogel's opinion relating to risk factors for ONJ included on Aredia labeling. Novartis, however, seeks to distinguish this labeling-related testimony from other labeling-related testimony that Aredia labels should or should not have included certain information or regarding drafting and approval of labeling.

In addressing Novartis's *Daubert* motions, the MDL court primarily denied Novartis's motion to exclude Dr. Vogel's testimony. With respect to Plaintiffs' general causation experts, including Dr. Vogel, the MDL court held that the parties' arguments "go to the weight of the experts' testimony not the admissibility." *In re Aredia & Zometa Prods. Liab. Litig.*, Civ. No. 06-MD-1760, 2009 WL 2497536, at *2 (M.D. Tenn. Aug. 13, 2009). The MDL court further held that "the parties have presented more than unsupported speculation . . . as to whether Aredia and Zometa can cause ONJ . . . Plaintiffs have satisfied their burden of establishing that their experts' general causation opinions are admissible under *Daubert* and Fed. R. Evid. 702." *Id*. With respect to Dr. Vogel specifically, the court further held that Dr. Vogel's "testimony concerning general causation and the scientific and medical accuracy of warnings given by Novartis is clearly more than unsupported speculation . . . [and] Plaintiffs have carried their burden of demonstrating that Dr. Vogel's testimony concerning general causation and the accuracy of warnings is admissible under *Daubert*." (Doc. No. 148 ("Vogel Odette Aff.") ¶ 3, Ex. 1 (*In re Aredia & Zometa Prods. Liab. Litig.* (M.D. Ten.. Aug. 13, 2009) (Doc. No. 2811)).) However, the MDL court explicitly did not consider "Dr. Vogel's opinions concerning the alleged corporate behavior of Novartis, his statement that the

delay and failure in transmission of certain information impacted a large number of patients, or his testimony concerning the benefit of pretreatment dental screening." *Id.*

First, the Court maintains its view articulated in the May 2014 Order with respect to the law of the case doctrine. (Doc. No. 202 at 12-13.) In sum, the Court concluded that while the law of the case doctrine is not automatic, the Court should not and will not disturb MDL court rulings in "the absence of a significant change of circumstances." (*Id.*) Here, there is no significant change of circumstances, and thus the MDL court's finding that Dr. Vogel's testimony concerning general causation and the scientific medical accuracy of warnings given by Novartis applies. This means that the MDL's determination that Dr. Vogel is qualified to opine on a number of issues based on his experience as an oncologist and hematologist with substantial experience treating patients with bone metastases, and is qualified to opine with respect to bisphosphonates, stands.

a. Novartis's corporate conduct

With respect to Novartis's corporate conduct, Novartis seeks to exclude Dr. Vogel's criticism of Novartis's response to ONJ reports and Novartis's labeling at that time. Specifically, Novartis seeks to exclude Dr. Vogel's testimony that Novartis: (1) misrepresented causation evidence; (2) referenced corticosteroid therapy as a potential risk factor for ONJ in the warnings on its label to misdirect medical attention from the jaw area; (3) minimized the incidence rate of ONJ; (4) knew and failed to communicate that ONJ occurs in a patient after fewer infusions of Zometa than Aredia; and (5) knew and failed to communicate that a decrease in the duration, dose and/or frequency of therapy decreases the incidence of ONJ. (Doc. No. 85 at 8 (citing Vogel Report at ¶ 62).)

Plaintiffs agree that they will not present Dr. Vogel's testimony regarding "state of mind, intent, or motives" of Novartis or of the FDA. (Doc. No. 147 at 4 n.4.) Even so, much of Novartis's memorandum outlines the myriad of reasons this Court should exclude the very testimony Plaintiff has agreed to not present. To the extent that this is the case, Novartis's motion to exclude Dr. Vogel's testimony on Novartis's corporate conduct is largely moot. Nonetheless, the Court will briefly outline the parameters of permissible testimony by Dr. Vogel on this subject.

The Court agrees with the parties that Dr. Vogel may not proffer an opinion relating to what individuals at Novartis thought about information found in certain internal documents or about their motivations regarding those documents. Expert testimony on "the intent, motives, or state of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *Deutsch*, 768 F. Supp. 2d at 442 (citing *In re Rezulin*, 309 F. Supp. 2d at 546).

This does not mean, however, that Dr. Vogel is precluded from referencing or relying on Novartis documents in any way. Novartis argues that Dr. Vogel's testimony, as it relates to Novartis documents, only presents speculative advocacy on Novartis's corporate conduct. The Court disagrees and declines to wholly exclude what Novartis has characterized as "corporate conduct" testimony. As the court concluded in *Deutsch*, testimony on Novartis's state of mind, intent, or motive is "distinct from whether Dr. Vogel can opine on his interpretation of whether certain information contained in the Novartis internal documents indicated certain risks and whether such information would have been useful to doctors." *Deutsch*, 768 F. Supp. 2d at 443. The latter type of

testimony is properly within Dr. Vogel's qualifications and expertise and "may be helpful [to a jury] in defining complex or specialized terminology, or drawing inferences that may not be apparent without the benefit or experience or specialized knowledge." *Id*. Specifically, it may be helpful to a jury to learn "what type of information a doctor expects to receive from the company advertising a drug and what information they are expected to and are able to ascertain on their own," and, "why including some risk factors and not others are misleading to a prescribing doctor." *Id*. In sum,

> Dr. Vogel can opine on the medicine and science that was available at the time regarding the risks and benefits of Aredia and Zometa, and can compare that information to what was disclosed on the label or in other materials Novartis presented to the medical community. To the extent the information on the known risks is derived from internal Novartis documents, Dr. Vogel's scientific expertise is helpful to the trier of fact in understanding those documents.

Id. To the extent Novartis is concerned about Dr. Vogel making "uniformed, erroneous assumptions," Novartis's concerns are properly addressed on cross-examination and do not go to the admissibility of Dr. Vogel's testimony. If, for example, Dr. Vogel failed to consider that Novartis does not manufacture corticosteroid medications, then Novartis may cross-examine Dr. Vogel on this issue. Thus, Novartis's motion on Novartis's "corporate conduct" is granted in part and denied in part.

b. Pre-bisphosphonate Treatment Dental Screening

Dr. Vogel opines that preventative dental measures prior to Aredia or Zometa treatment reduce the incidence of ONJ. Novartis argues that Plaintiffs cannot lay the appropriate foundation to support Dr. Vogel's testimony on this issue. Specifically, Novartis argues that Dr. Vogel is not qualified to present such testimony and that the

methodology he uses is not scientifically reliable as it is based on a single, inconclusive article.

Other courts have held that Dr. Vogel is qualified and has a reliable basis with respect to pretreatment dental screening by his "extensive experience as an oncologist and hematologist including treating patients with bisphosphonate therapy . . . ." *Deutsch*, 768 F. Supp. 2d. at 437. As the court reasoned in *Bowles & Sheffer*, "there is significant medical literature pointing to the benefits of pretreatment screening," including from Novartis itself. *Mathews v. Novartis Pharm. Corp.*, Civ. No. 12-314, 2013 WL 5780415, at *22 (S.D. Ohio October 25, 2013) (citing to the same court's September 20, 2013 decision in two related cases *Bowles* (Civ. No. 12-145) and *Sheffer* (Civ. No. 12-238), which is attached to its decision as Exhibit 1 and is incorporated by reference) ("*Bowles & Sheffer*"). The Court agrees. Thus, Dr. Vogel's opinion is based on sufficient, reliable facts or data.

However, the Court also agrees with the court's determination in *Brodie*, which deemed admissible Dr. Vogel's pre-treatment dental screening, "assuming a sufficient foundation can be established, of which the Court is dubious." (Vogel Odette Aff. ¶ 3, Ex. 5 (*Brodie v. Novartis Pharm. Corp.*, Civ. No. 10-138 at 3 (E.D. Mo. Jan. 20, 2012)).) The Court therefore reserves the right to exclude testimony on this matter should Plaintiffs fail to establish sufficient foundation. Certainly, Dr. Marx is better positioned

to testify to this issue, and the Court has already admitted his testimony in this regard. (*See* Doc. No. 202 at 13-14.)[7]

c. ONJ incidence

Dr. Vogel opines that the incidence rate of ONJ in patients taking bisphosphonates is "generally five percent or above." (Vogel Report at ¶ 47.) Novartis argues that this testimony should be excluded because: (1) it is a corporate conduct opinion; (2) it does not "fit" the facts of the case because it relates to Zometa and not Aredia; (3) it is based on insufficient facts or data; and (4) the methodology is flawed. In sum, Novartis argues that Dr. Vogel's opinion is unreliable. The Court disagrees.

A number of courts have allowed Dr. Vogel to testify to ONJ incidence rate. (Vogel Odette Aff. ¶ 3, Ex. 4 (*Mahaney v. Novartis Pharm. Corp.*, Civ. No. 06-35 (W.D. Ky. Sept. 9, 2011)) ("Vogel's statements on the incidence rate of ONJ are admissible."); *Deutsch*, 768 F. Supp. 2d at 441 (allowing opinion testimony that the incidence rate of ONJ was generally five percent or above); *Davids v. Novartis Pharm Corp.*, 857 F. Supp. 2d 267, 275-76 (E.D.N.Y. 2012) (adopting *Deutsch* for a number of experts, including Dr. Vogel, and explaining that Novartis's attempts to differentiate *Davids* from *Deutsch* fail); *Earp v. Novartis Pharm. Corp.*, Civ. No. 11-680, 2013 WL 48544488, at *4 (E.D.N.C. Sept. 11, 2013) (finding Dr. Vogel qualified to testify on incidence rate of ONJ); *Bowles & Sheffer*, 2013 WL 5780415 at *22-23 (allowing Dr. Vogel to testify on the five percent incidence rate and holding that Novartis's

[7] Novartis also contests "fit" in this case. However, this is a question of fact for the jury, and Plaintiffs have presented evidence that Kruszka would have benefitted from additional pretreatment dental screening.

objections go to weight and not admissibility of his opinions); *Georges v. Novartis Pharm. Corp.*, Civ. No. 06-5207, 2013 WL 5217198, at *15 (C.D. Cal. Apr. 4, 2013) (denying Novartis's *Daubert* motion on Dr. Vogel with respect to incidence of ONJ testimony); *Taylor*, 2013 WL 5118945, at *4 (allowing Dr. Vogel's testimony on the incidence rate of ONJ, except to the extent he would opine on whether Novartis sought to minimize the incidence rate, which addresses motive or intent).

The Court agrees with these cases and finds that Dr. Vogel may opine that the incidence rate of ONJ was five percent or greater, and that he has an adequate and reliable basis for this opinion based on his background, experience, and his analysis of a number of publications. Novartis's generalized issues relating to the reliability and methodology of Dr. Vogel's opinion on ONJ incidence do not affect the admissibility of his opinion. (*See* Vogel Odette Aff. ¶ 3, Ex. 4 (*Mahaney*, Civ. No. 06-35 (W.D. Ky. Sept. 9, 2011).) Therefore, Dr. Vogel's opinions will not be excluded on these grounds.

Novartis seeks to differentiate this case from those that have allowed Dr. Vogel's incidence testimony based on the fact that his opinions involve Zometa, and Kruszka only took Aredia. This does not render Dr. Vogel's testimony inadmissible. Portions of Dr. Vogel's expert report address both Aredia and Zometa, including testimony about labeling which is similar for both drugs. On the simplest level, both drugs are Novartis-manufactured bisphosphonates used in the treatment of myeloma. To the extent that there are chemical, labeling, or other differences, those issues too are best addressed through cross-examination and do not go to admissibility. Thus, the Court also declines to exclude Dr. Vogel's opinions on this basis.

Accordingly, Dr. Vogel can opine that the incidence rate of ONJ was generally five percent or above in accordance with the limitations detailed above, and Novartis's motion on this issue is denied.

d. Alternative Dosing-Duration regimens

Dr. Vogel opines on the efficacy of a reduced dosing schedule and that additional information on dosing should have been provided to patients. Novartis argues this is not supported by FDA recommendations and that the sole study ("Corso Study"[8]) Dr. Vogel cites is scientifically unreliable. Also, Novartis relies on the decision in *Brodie*, wherein the court excluded the same testimony because the topic was outside Dr. Vogel's area of expertise and was not based on scientifically reliable sources. (Vogel Odette Aff. ¶ 3, Ex. 5 (*Brodie*, Civ. No. 10-138 (E.D. Mo. Jan. 20, 2012)).)

Here, Dr. Vogel's reliance on the Corso Study provides some scientific basis for his opinion, and Dr. Vogel is qualified to opine on the results of the study based on his expertise as an oncologist and hematologist, including treating patients with bisphosphonate therapy. As the court stated in *Deutsch*,

> [T]he MDL court stated that Dr. Vogel was qualified to opine on whether the information provided to the medical community, including information on dosing, was false or misleading. Furthermore, the MDL court has also ruled on the admissibility of Dr. Vogel's opinions that are based on the relevant medical literature. . . . Accordingly, the MDL court implicitly found Dr. Vogel qualified to interpret [observational] studies . . . .

Deutsch, 768 F. Supp. 2d at 444. Also, "[w]hether the results of the Corso study are sufficiently verified or whether subsequent studies have reached different results goes to

[8] A. Corso, et al., *A Different Schedule of Zoledronic Acid Can Reduce the Risk of Osteonecrosis of the Jaw in Patients with Multiple Myeloma*, 21 Leukemia 1545 (2007).

the weight rather than the admissibility of the testimony and may be explored on cross examination." *Taylor*, 2013 WL 5118945, at *5 (citing *Deutsch,* 768 F. Supp. 2d at 437). The Court agrees with this conclusion. Accordingly, the Court denies Novartis's motion as to dosing and duration for Dr. Vogel.

e. Biological Mechanisms

Dr. Vogel opines that bisphosphonates are more likely to accumulate in the jaw than other bones. Novartis seeks to exclude this opinion on the basis that Dr. Vogel lacks the requisite expertise to address the issue because he has admitted he is not a bone biologist or pathologist. Novartis appears to rest its argument on the fact that the *Brodie* court excluded Dr. Vogel's testimony on this issue. (*See* Vogel Odette Aff. ¶ 3, Ex. 5 (*Brodie,* Civ. No. 10-138 (E.D. Mo. Jan. 20, 2012)).)

In *Brodie*, the court held, without further explanation, that, "Dr. Vogel has admitted that he is not an expert on bone biology and, therefore, he is unqualified to opine on how bisphosphonates affect bone. As such, he is precluded from opining on [this area]." (*Id*. at 3.). However, other courts have admitted the same testimony. For example, in *Deutsch* the court found that "Dr. Vogel's lack of expertise as a bone biologist or bone pathologist does not disqualify him from opining on a plausible causation mechanism involving how bisphosphonates target bone to cause BRONJ." *Deutsch*, 768 F. Supp. 2d at 439. The court found that his educational and experiential qualifications were closely related and that he has substantial experience treating patients with bone metastases. *Id*. Finally, the court noted that Dr. Vogel "is not proffering this opinion as the definitive mechanism, but rather for the proposition that it is a plausible

mechanism that has been identified based on his professional understanding of the relevant literature." *Id*.

Here, the Court finds that there are no material legal or factual differences between the motion that was before the court in *Deutsch* and the motion now before this Court with respect to this topic. Therefore, the Court finds the thorough reasoning of *Deutsch* persuasive and adopts it here. *See id.* at 439-40; *see also Georges*, 2013 WL 5217198, at *15 (adopting *Deutsch* and denying Novartis's request to exclude testimony on biological mechanisms); *Davids*, 857 F. Supp. 2d at 273, 276 (same); *Bowles & Sheffer*, 2013 WL 5780415, at *23 ("In admitting Dr. Vogel's testimony concerning general causation . . . the MDL Court has already impliedly held that Dr. Vogel is qualified to testify on this topic [of biological mechanisms.") Accordingly, Novartis's motion as to this area of testimony is denied.

II. Plaintiffs' Motion in *Limine* to Exclude Testimony of Duplicative Defense Experts

Plaintiffs seek to preclude Novartis from submitting cumulative testimony from multiple experts. At the time of filing this motion, Novartis had offered fourteen experts. (Doc. No. 208 (6/10/14 Hearing Tr.) at 16.) At the time of this Court's hearing on the motion, the parties had agreed to withdraw the following experts: (1) Dr. Ronald Bukowski; (2) Dr. Paul Bunn; (3) Dr. Serge Ferrari; (4) Dr. Thomas Flynn; (5) Dr. Peter Krakowiak; and (5) Dr. Socrates Papapoulos. (*Id*. at 16.)

Plaintiffs still seeks to limit Novartis's experts. (Tr. at 17.) However, the parties have agreed to continue to work together to determine which experts will be offered at

trial. (Tr. at 18-26.) The Court has agreed to address this issue at the July 16, 2014 pre-trial, should the parties be unable to agree to an acceptable number of Novartis's experts, and thus issues regarding the number of experts remain. (Tr. at 25-26.) Accordingly, the Court dismisses this motion without prejudice as moot and reserves the right to address issues relating to the cumulative and duplicative nature of Novartis's expert testimony should it need to do so.

III. Plaintiffs' Motion to Unseal the Second Declaration of Robert Germany and Exhibits 1-182

Plaintiffs seek the unsealing of the Declaration of Robert Germany ("Germany Declaration") and the attached 182 exhibits ("Germany Exhibits") which include articles, Novartis corporate documents, and certain information sent to the public. The Germany Declaration and Germany Exhibits are under seal on the basis of the Protective and Confidentiality Order ("Confidentiality Order") the MDL court put into place on August 15, 2006. (Doc. No. 136 ("Ex. Index") ¶ 1, Ex. 1.) The Confidentiality Order was entered in all MDL cases. The Confidentiality Order allows the parties to designate certain documents "confidential" to be filed under seal and kept protected. The Confidentiality Order includes a time line for contesting confidentiality designations.

Novartis does not dispute that documents that have been published at prior trials are no longer confidential. Specifically, Novartis agrees that all but sixty-seven of the 182 Germany Exhibits are no longer confidential. (Ex. Index ¶ 2, Ex. 2.) Thus, the Court agrees that those Germany Exhibits which have been published at previous trials, and which do not include those sixty-seven Germany Exhibits listed by Novartis, are no

longer confidential under the Confidentiality Order and can be filed publicly.[9] The Court also concludes that any additional exhibits that have been admitted at any trial, even if not published, but which were not identified by Novartis as no longer confidential, are also no longer confidential and can be filed publicly.[10]

For the remaining Germany Exhibits never admitted at any trial and for which the confidentiality status is disputed, there is a common-law right of access to judicial records. *See Webster Groves Sch. Dist. v. Pulitzer Publ'g Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990). However, the Eighth Circuit does not recognize the strong presumption favoring access adopted by some circuits and thus the Court must "weigh the competing interests" of the parties in determining whether to unseal court records. *Id*. n.4. The interest in protecting a company's internal information can warrant sealing of records. *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 245 F.R.D. 632, 636 (D. Minn. 2007).

Plaintiffs argue that the remaining sixty documents are all at least seven years old and thus any potentially competitive information has expired. Plaintiffs further argue that keeping the materials under seal stretches the Confidentiality Order beyond the intended

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[9] Those exhibits which Novartis admits have been published at prior trials and are no longer confidential include the following exhibits: 1-7, 9-19, 21-25, 27, 29-37, 39-53, 56, 59, 61-65, 67, 72-74, 76-79, 84-87, 90, 92, 93, 95-97, 100, 101, 103-105, 107, 110, 111, 113-118, 120, 121, 124, 125, 127, 129, 131, 133, 135, 137, 139, 140, 144, 145, 147, 149, 151, 153, 156-58, 164, 165, 170, 171, 173, 174, and 182.

[10] For example, Plaintiffs indicate that Exhibit 71 (an e-mail from Spet to Hei) was admitted at a number of previous trials. That exhibit should not remain under seal. (Doc. No. 178 ("Odette Aff.") ¶ 3, Ex. A.)

scope and frustrates the public interest of keeping information in the public domain. As a result, Plaintiffs contend that these documents should be made public.

Novartis argues that the weighing of competing interests favors non-disclosure because the pharmaceuticals industry is highly competitive, and, as such, any internal documents holding competitive information must remain sealed. Novartis further points to the untimeliness of Plaintiffs' motion and the fact that a number of courts have declined to wholesale unseal all of the Germany Exhibits.

At oral argument, the parties represented to the Court that the unsealing of the approximately sixty documents will have little practical effect on the trial. Novartis explained that the documents in dispute have not been used in previous trials, and likely will not be used at this trial, thereby making the review of the confidentiality status of any of those documents practicable for the Court on a case-by-case basis. The Court agrees.

The MDL Confidentiality Order is controlling here for those documents not already made public, and Plaintiff provides no persuasive reason to deviate from it at this juncture. While the Court recognizes the interest of having the documents at issue here public, when weighing competing interests the Court concludes that ongoing protection is merited. First, Plaintiffs have had a number of opportunities—with the MDL court, in other cases, and in this case—to dispute the designations of the documents at issue but have failed to do so. Second, without a document-by-document analysis, the Court cannot determine whether documents, even those dating from 2007, contain confidential competitive information. The Court need not engage in that analysis here based on a

number of factors: (1) the parties have represented that the documents will not likely be introduced at trial; (2) to date, the parties have always agreed on the designation of documents for trial amongst themselves; and (3) if the documents are introduced at trial, the Court can adequately examine their confidentiality status at that time. Therefore, the Court declines to undo the Confidentiality Order at this late phase in the proceedings and will examine the remaining disputed exhibits on an as-needed basis. The Court notes that should such a situation arise at trial, Novartis will have to justify the sealing of the documents at issue.

Plaintiffs' specifically request that the expert reports of Dr. Arrowsmith and Dr. Feigal be unsealed because they have already been made public. The Court agrees. Dr. Arrowsmith's and Dr. Feigal's reports may be unsealed in a manner consistent with the above ruling.

In sum, those documents already made public through admission at prior trials will be unsealed per the agreement of the parties, and all documents not yet public will remain sealed. The Court will address any remaining exhibits on a document-by-document basis during the trial, as needed, but declines to unseal all of them at this stage.

ORDER

Based on the foregoing, and all the files, records, and proceedings here, **IT IS HEREBY ORDERED** that:

1. Plaintiffs' Motion to Exclude Expert Testimony of Dr. Carol Ann Huff (Doc. No. [72]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Dr. Huff's testimony relating to treating myeloma, prescribing Aredia and Zometa to treat myeloma, the immunosuppressive effect of myeloma-related treatments, the specific effects of Aredia treatment, and also Kruszka's clinical course of treatment are admissible to the extent they are consistent with this Memorandum Opinion;

b. Dr. Huff's specific causation testimony is limited in a manner consistent with this Memorandum Opinion; and

c. Dr. Huff will not be permitted to testify to information contained in the Huff Declaration, but not contained in the Huff Report.

2. Plaintiffs' Motion to Exclude Testimony of Dr. Dale A. Baur (Doc. No. [81]) is **GRANTED** to the extent he seeks to testify on the following topics: (1) whether the benefits of bisphosphonate therapy outweigh the risks; (2) whether bisphosphonate therapy improves quality of life; and (3) whether the warnings disseminated with Novartis's bisphosphonate drugs were effective, timely, or appropriate.

3. Plaintiffs' Motion to Exclude Expert Testimony Relating to Alleged FDA Compliance and/or Novartis's "State of Mind" (Doc. No. [97]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Drs. Arrowsmith and Feigal are precluded from testifying to the state of mind, intent or motives of Novartis or the FDA; but

b. Drs. Arrowsmith and Feigal testimony relating to the reasonableness of Novartis's interaction with the FDA and compliance with

FDA regulations, including with respect to labeling and warnings is admissible.

4. Defendant's Motion to Exclude Expert Testimony of Dr. Suzanne Parisian (Doc. No. [46]) is **GRANTED IN PART** and **DENIED IN PART** consistent with the Court's detailed instructions in this Memorandum Opinion;

5. Defendant's Motion to Exclude Testimony of Plaintiffs' Expert Dr. Keith Skubitz (Doc. No. [54]) is **DENIED AS MOOT**;

6. Defendant's Motion to Exclude Expert Testimony of Plaintiffs' Expert, Prof. Wayne Ray (Doc. No. [56]) is **DENIED AS MOOT**;

7. Defendant's Motion to Exclude Expert Testimony of Dr. James Vogel (Doc. No. [79]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Dr. Vogel's testimony relating to the state of mind, intent or motives of Novartis is inadmissible, but Dr. Vogel's testimony relating to his interpretation of whether certain information contained in Novartis's internal documents indicated certain risks and whether such information would have been useful doctors is admissible, subject to the limitations outlined in detail in this Memorandum Opinion;

b. Dr. Vogel's pre-treatment dental screening testimony is admissible;

c. Dr. Vogel can opine that the incidence rate of ONJ was generally five percent or above in accordance with the limitations detailed in this Memorandum Opinion;

d. Dr. Vogel can opine on dosing and duration in accordance with the limitations detailed in this Memorandum Opinion;

e. Dr. Vogel can opine on biological mechanisms in accordance with the limitations detailed in this Memorandum Opinion;

8. Plaintiffs' Motion *in Limine* to Exclude Testimony of Duplicative Defense Experts (Doc. No. [43]) is **DENIED WITHOUT PREJUDICE AS MOOT**; and

9. Plaintiffs' Motion to Unseal the Second Declaration of Robert G. Germany and Exhibits 1 - 182 (Doc. No. [109]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Those documents admitted in any previous trials are public and are unsealed; and

b. Those documents not previously admitted will remain under seal and will be addressed by this Court at trial on a case-by-case basis.

Dated: July 1, 2014

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge