UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION
CASE NO. 1:06-CV-00035-R

NATASHA KYLE MAHANEY
on behalf of estate of Pamela Kay Kyle **PLAINTIFF**

v.

NOVARTIS PHARMACEUTICALS CORP. **DEFENDANT**

MEMORANDUM OPINION AND ORDER

This matter is set for trial on January 9, 2012. In anticipation of the final pretrial conference, the parties have filed a number of motions in limine. These motions have been fully briefed and are now ripe for adjudication. Below is the Court's ruling on each of these matters.

I. BACKGROUND

Zometa and Aredia are two FDA-approved intravenous bisphosphonate ("IV BP") drugs, manufactured by Defendant Novartis Pharmaceuticals Corporation ("NPC"). Both are used to combat a variety of advanced cancers that have presented themselves in patients' bones. Within cancer patients suffering this type of affliction, BP drugs like Zometa and Aredia are widely used.

Pamela Kay Kyle ("Kyle") was diagnosed with breast cancer in 1997, which later metastasized to her skull. Her oncologist prescribed Zometa in October of 2003 as part of her treatment and she continued taking it until November 4, 2004. Kyle succumbed to her cancer on October 1, 2008.

Plaintiff Natasha Kyle Mahaney ("Plaintiff") brings this action against NPC on behalf of Kyle's estate. Plaintiff alleges that prior to her death, Kyle developed osteonecrosis of the jaw ("ONJ"). ONJ is a condition that results in the necrosis (or death) of jaw bone. Plaintiff claims

the type of ONJ that Kyle contracted was caused by IV BP drugs, commonly referred to as either bisphosphonate-related ONJ ("BRONJ"), bisphosphonate-induced ONJ ("BIONJ"), or bisphosphonate ONJ ("BONJ"). Plaintiff pursues this action under the state-law theories of strict liability, negligence, and breach of implied warranties. Her principal complaint is NPC failed to adequately warn Kyle of Zometa's dangers and side effects.

II. STANDARD

Motions in limine provided in advance of trial are appropriate if they eliminate evidence that has no legitimate use at trial for any purpose. *Jonasson v. Lutheran Child & Family Serv.*, 115 F.3d 436, 440 (7th Cir. 1997); *Bouchard v. Am. Home Products Corp.*, 213 F. Supp. 2d 802, 810 (N.D. Ohio 2002) ("The court has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds." (citing *Luce v. United States*, 469 U.S. 38, 41 n. 4 (1984)). Only where the evidence satisfies this high bar should the court exclude it; if not, "rulings [on evidence] should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Gresh v. Waste Serv. of Am., Inc.*, 738 F. Supp. 2d 702, 706 (E.D. Ky. 2010) (quoting *Indiana Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). Even if a motion in limine is denied, the court may revisit the decision at trial when the parties have more thoroughly presented the disputed evidence. *See id*. ("Denial of a motion in limine does not guarantee that the evidence will be admitted at trial, and the court will hear objections to such evidence as they arise at trial.").

III. DISCUSSION

1. Statements by fact witnesses (DN 106)

NPC moves to exclude portions of the testimony by Kyle, Plaintiff, and Kyle's best

friend, Pamela Lowe. The Court will address the relevant background, the offered objections, and its decisions.

a. Pamela Kay Kyle's testimony

Before her death, Kyle gave a videotaped deposition. Plaintiff will offer it into evidence at trial. NPC references portions of Kyle's deposition it hopes to strike. *See* Kyle Depo p. 118-121, DN 106-2, p. 17-20. Here, Kyle makes statements that she discontinued her use of Zometa because it made her bones "too hard." The pertinent testimony that concerns the Court is as follows:

> NPC Counsel's Question. So the reason that you asked to discontinue the Zometa is because you were concerned that your bones were getting too hard?
> Kyle Answer. That's correct.
> Q. What caused you to think that it was the Zometa that was related to that issue?
> A. With Zometa being, I guess, a bone strengthener, that would imply that it would make the bones harder and less likely to injure. So I guess just common sense kind of put me to that deduction, that it was the Zometa that had made it so hard.
> Q. But that was not based on any research that you had done on your own at that time --
> A. No.
> Q. -- that was just your own assumption?
> A. Correct.
> Q. Was that based on anything that you had been told by any doctors?
> A. Not that I can recall.
> . . .
> Q. Did you have any discussions at that point about other potential side effects of Zometa other than the possibility that it might be causing your bones to become hard?
> A. Not that I can recall.

Kyle Depo. p. 119-21, DN 106-2 at 18-20. NPC moves to exclude this testimony because Kyle is unqualified to give opinions on medical causation and this is not a proper lay opinion under Federal Rule of Evidence 701. Plaintiff responds that Kyle's statements are consistent with the testimony of her physicians and that the jury is entitled to know her subjective impression of

why she stopped taking the Zometa.

Under Rule 701, a lay witness may provide opinion testimony only when such opinions are "(a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge . . . ." Fed. R. Evid. 701. "The primary purpose of Rule 701 is to allow nonexpert witnesses to give opinion testimony when, as a matter of practical necessity, events which they have personally observed cannot otherwise be fully presented to the court or the jury." *Randolph v. Collectramatic, Inc.*, 590 F.2d 844, 846 (10th Cir. 1979) (citation omitted). Trial courts are afforded broad discretion when admitting lay opinion testimony. *Heritage Mut. Ins. Co. v. Reck*, 127 F. App'x 194, 199 (6th Cir. 2005).

Kyle's statement that Zometa "caused" her bones to harden is inadmissible opinion evidence under Rule 701. Kyle could not have perceived the changes in her bone density, and while she may have "felt" changes to her body during the Zometa treatment, the advanced stage of her cancer and the presence of other medical procedures during the same time frame substantially undermine the reliability of her statements. Ergo, the previously quoted passage on causation represents improper testimony. This ruling does not affect statements by Kyle about why she stopped taking Zometa that are not linked to medical causation.

b. Plaintiff Natasha Kyle Mahaney's testimony

Before her death, Kyle was diagnosed with trigeminal neuralgia, a condition unrelated to her ONJ. Kyle Depo. p. 18-21, DN 106-2 at 4-7. Trigeminal neuralgia is a syndrome characterized by "severe, episodic pain in the area supplied by the trigeminal nerve." *Trigeminal Neuralgia Definition*, Dorlands.com, http://www.dorlands.com/def.jsp?id=100071619 (last

visited October 11, 2011). The trigeminal nerve is located in and around a person's jaw. Kyle testified in her deposition that this condition may have caused some of her jaw pain before the apparent onset of ONJ. Kyle Depo. p. 102-05, DN 106-2 at 12-15. She was able to differentiate, to a degree, between the pain caused by her trigeminal neuralgia and the ONJ.

NPC now moves to limit Plaintiff's direct testimony on three bases. The first two mirror the objections previously raised against Kyle's testimony: Plaintiff is not an expert on Zometa, ONJ, or medicine and is therefore unqualified to offer statements about causation or the effects of Zometa. The Court declines to answer these objections at present. Whereas Kyle's testimony is static since it has been prerecorded, Plaintiff will testify at trial and thus it is difficult to predict how these statements will present themselves. NPC may offer these objections at trial should the need arise. The Court will, however, issue a warning to Plaintiff: she is not an expert on causation and her opinions on Zometa and ONJ do not meet the requirements of Rule 701. Statements to that effect, absent a close nexus to the non-hearsay remarks of Kyle's physicians, are inadmissible.

NPC also argues that given Kyle's trigeminal neuralgia, Plaintiff cannot distinguish between the pain Kyle suffered as a result of this condition as opposed to the ONJ. NPC says Plaintiff should be precluded from offering testimony on the pain in Kyle's mouth because it invites speculation. The Court rejects such a contention - this is a legitimate basis for undermining Plaintiff's testimony on cross examination but not its exclusion. Plaintiff may also testify about personally observing Kyle's difficulty eating and brushing her teeth. Finally, regarding Kyle's statements about having pain in her mouth, this evidence might be admissible under the hearsay exception of a then-existing "state of mind, emotion, sensation, or physical

condition." Fed. R. Evid. 803(3). Since the Court has not confronted this testimony directly, the Court does not decide if it is admissible; instead, it opts to do so at trial.

Simply put, Plaintiff may testify on what she observed and the subjects about which she has personal knowledge. She may not speak to causation or why she thinks Zometa and NPC are responsible for her mother's injuries. Plaintiff is not qualified to give such opinions and the Court warns her against straying into these areas.

c. Pamela Lowe's testimony

Lowe offers deposition testimony that she and Kyle were close friends for more than twenty years. In the final months of Kyle's life, Lowe provided day-to-day care for her, including most of her dental hygiene. Lowe says she noticed a foul odor coming from Kyle's mouth and that her teeth had a general discoloration and "rotting" quality. In her deposition, Lowe is candid that she is not a doctor and unqualified to draw a causal connection between Zometa and the condition of Kyle's mouth prior to her death.

NPC explains that any attempt for Lowe to offer statements on causation is improper because she lacks the requisite medical or scientific background. Lowe's testimony must be limited to her own, personal observations. She is permitted to describe Kyle's pain to the extent she observed it and such statements meet prerequisites of Rule 803(3). She is allowed to testify about any disfigurement Kyle experienced. Lowe may not testify on the causation between Zometa and ONJ. Lowe is further precluded from opining on what caused Kyle's pain or disfigurement.

During her deposition, Lowe said the cause of Kyle's death was ultimately starvation. NPC contends this statement is inadmissible since it falls outside a layperson's opinion provided

for in Rule 701. The Court agrees. As noted, Lowe is not a medical expert and the causes of Kyle's death are not a subject properly confronted by a lay witness under Rule 701. Lowe may offer testimony about her personal observations, such as the changes in Kyle's appearance preceding her death and the condition and smell of Kyle's mouth. She may testify on statements Kyle made to her about the pain in her jaw, so long as they meet Rule 803(3)'s hearsay exception.

NPC targets statements Lowe makes about Kyle's state of mind, such as how she felt about her jaw problems and the instant lawsuit. Lowe Depo. p. 77, 86, DN 106-7 at 27, 33. It alleges these portions of her testimony should be excluded. Although this testimony contains the hallmarks of inadmissible hearsay and conjecture, the Court will wait for trial and the manner in which it is offered to the jury before rendering a decision.

d. Summary of testimony for Plaintiff Natasha Kyle Mahaney and Pamela Lowe

The Court ends this ruling with the following advice: Plaintiff's counsel should first approach the bench before soliciting information from Plaintiff or Lowe that could arguably be characterized as causation or expert-related testimony. Statements of this ilk from these individuals will not be tolerated as these lay witnesses are not qualified to provide these opinions.

2. Exclude evidence on incorrect legal standards (DN 107)

NPC moves to preclude Plaintiff from presenting evidence or arguments that imply it had a duty to warn anyone but Kyle's treating physician (Dr. Steven Smith) about the alleged risks of Zometa. It cites the Kentucky Supreme Court decision of *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004), for the proposition that pharmaceutical companies are relieved from liability where they have provided an adequate warning to the prescribing physician. NPC thereby concludes it

is contrary to the applicable law for Plaintiff to argue NPC is liable for failing to warn Kyle's dentist, oral surgeon, periodontist, or her other health care providers.

In *Larkin v. Pfizer, Inc.*, the Sixth Circuit Court of Appeals reviewed a products liability action under Kentucky law where the plaintiff had suffered an adverse reaction to two medications prescribed by his physician. The record in the lower court established the plaintiff's physician was warned by Pfizer's literature that the adverse reaction was a possible side effect. *Id*. at 760. On appeal, the Sixth Circuit certified the following question to Kentucky's highest court:

> Whether the learned intermediary doctrine should apply in Kentucky to a case involving an allegation that a manufacturer of a prescription drug failed to warn the ultimate consumer of risks associated with that drug, even though the manufacturer informed the prescribing physician of those risks?

Id. at 761. The court answered in the affirmative, describing the newly adopted rule as follows:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Id. at 762 (quoting Restatement (Third) of Torts: Prods. Liab. § 6(d) (1998)) (formatting altered). Courts within Kentucky's borders have relied on *Larkin* to immunize drug manufacturers from liability when physicians were adequately warned about potential side effects. *E.g.*, *Smith v. Smithkline Beecham Corp.*, No. 10-CV-73-ART, 2010 WL 3432594, at *3 (E.D. Ky. Aug. 30, 2010); *Gibson v. Sanofi-Aventis U.S., LLC*, No. 3:07-CV-192-S, 2009 WL 3490454, at *4 (W.D. Ky. Oct. 27, 2009).

Underlining certain passages, NPC says *Larkin* opted for the restrictive view of the

learned intermediary rule that states pharmaceutical companies are only required to warn a patient's prescribing physician. While this argument is not completely disjointed from the opinion's language, the Kentucky Supreme Court's holding was unambiguous: "we now adopt Restatement (Third) of Torts: Products Liability § 6(d) (duty to warn of possible side effects satisfied if adequate warning given to patient's health care provider, subject to exceptions)."[1] *Larkin*, 153 S.W.3d at 770. Thus, the restatement's requirements should guide this opinion rather than the self selected passages of *Larkin* provided by NPC. In addition, Kentucky's highest court emphasized that *Larkin* was not the final word on the learned intermediary rule, as "the posture of the case [did] not require [the court] to decide which, if any, of the recognized exceptions to this rule should be adopted . . . ." *Id*. at 770. For that reason, the Court believes the Kentucky Supreme Court did not mean for *Larkin* to be the first and only chapter in the doctrine's development.[2]

Beginning with the restatement's language, the learned intermediary rule provides cover to pharmaceutical companies who have given reasonable instructions to "prescribing *and other health-care providers* who are in a position to reduce the risks of harm in accordance with the instructions or warnings." Restatement (Third) of Torts: Prods. Liab. § 6(d)(1) (1998) (emphasis

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[1] In its reply to this motion, NPC alleges the *Larkin* court merely "cited" to the Restatement (Third) of Torts. Reply Mot., p. 2, DN 145 at 2. Such a reading is incorrect considering the decision's last paragraph.

[2] Insofar as this issue is an unresolved question of Kentucky law, the Court abides by the normal tools to answer such a query. "In its determination of a question unanswered by state law, it is appropriate for the federal court to consider analogous state cases and relevant dicta, the restatement of law, law review commentaries and decisions of other jurisdictions or the 'majority rule.'" *Guarantee Elec. Co. v. Big Rivers Elec. Corp.*, 669 F. Supp. 1371, 1377 (W.D. Ky. 1987). In the absence of analogous authority from Kentucky's courts, a federal district court within its borders should look to other jurisdictions for guidance. *See id*.

added); *see Larkin*, 153 S.W.3d at 762. The restatement's commentary continues in this vein with the following:

> Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to nonprescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.

Id. § Comment D. Accordingly, the restatement's text and commentary debunk NPC's assertion that Kentucky's version of the learned intermediary rule excludes all other physicians save the one actually prescribing the medicine in issue.

Not surprisingly, other courts considering the issue have applied the learned intermediary rule to nonprescribing physicians. In *Holley v. Burroughs Wellcome Co.*, 330 S.E.2d 228 (N.C. Ct. App. 1985), the North Carolina Court of Appeals reviewed a case where a patient was injured while receiving anesthesia from a nurse anesthetist, working under a doctor's supervision. In the lawsuit against the drug manufacturer for failing to warn of the anesthetic's side effect, the court decided the manufacturer should have extended its warnings to the nurse along with the primary heath care professional. *Id*. at 746-47. Such a conclusion followed because the requirement that a pharmaceutical company should "provide adequate warnings regarding its products to the 'medical profession,' ought to apply [. . .] to other health care professionals using the products." *Id*. at 747. Similar decisions were reached in *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 92-93 (Tex. App. 2000) and *Rohrbough by Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 478-79 (N.D. W.Va. 1989), where the courts extended the learned intermediary rule to cover nurses both prescribing and not prescribing medicine. Therefore, a broader take on the rule's application and protections permeates the legal landscape, in contravention of NPC's arguments.

In fact, courts interpreting this very motion have declined to adopt NPC's view of the learned intermediary rule. Zometa and its supposedly inadequate labeling have been the targets of several lawsuits prior to this one. In *Stevens v. Novartis Pharm. Corp.*, 247 P.3d 244, (Mont. 2010), the Montana Supreme Court reviewed, among other things, whether the state's learned intermediary rule prohibited the plaintiff from pursuing the theory that NPC should have warned health care providers besides the prescribing physicians. *Id*. at 257-59. After reviewing the language from the Restatement (Third) of Torts and comparing it to other legal decisions interpreting the doctrine, the court found "Novartis' duty to warn . . . would presumably include at least the [group of treating oncologists] who counseled Stevens on dental surgery, if not the nurses who routinely administered Zometa . . . ." *Id*. at 260. An identical conclusion was reached in *Hogan v. Novartis Pharm. Corp.*, No. 06-CV-0260, 2011 WL 1533467, at *8-10 (E.D.N.Y. April 24, 2011). There, Judge Cogan denied NPC's attempts to limit the scope of its duty to warn under the learned intermediary rule. In so deciding, he found that none of the cases upon which NPC had relied for its narrow interpretation stood "for the proposition that prescribing physicians are the *only* treating medical professionals who must be warned." *Id*. at *9 (emphasis in original). Perhaps most persuasive to this Court is both *Hogan* and *Stevens* employed section 6(d) of the Restatement (Third) of Torts, the version adopted by the Kentucky Supreme Court in *Larkin*, in reaching their conclusions. *See id*. at *10; *Stevens*, 247 P.3d at 257.

The above-cited decisions, in tandem with the section 6(d)'s plain language, lead the Court to reject NPC's motion. It is impossible to read the learned intermediary rule through NPC's proposed lens given the interplay between multiple physicians, numerous procedures, and countless drugs to which cancer patients are subjected. Nevertheless, the Court limits this

opinion to the specific facts of this case; it is not endorsing a view that all medical professionals should be forewarned of a drug's potential side effects or deciding what procedures a pharmaceutical company should follow to meet such a requirement. Rather, under these particular circumstances, the Court finds NPC's limiting instruction inappropriate and will reject this motion.

3. Exclude certain corporate documents (DN 110)

NPC asks the Court to exclude twelve documents, mainly emails, because they are irrelevant evidence, their probative value is substantially outweighed by undue prejudice, and they constitute inadmissible hearsay. In support of these assertions, the motion references Federal Rules of Evidence 401, 403 and 801.

Evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence which the Court finds irrelevant is inadmissible. Fed. R. Evid. 402. Courts however have set the bar relatively low for relevancy under Rule 401. *See Churchwell v. Bluegrass Marine, Inc.*, 444 F.3d 898, 905 (6th Cir.2006) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 587 (1993)). If the evidence "tend[s] to prove the matter sought to be prove[d]," then it satisfies this the rule's threshold. Fed. R. Evid. 401 (advisory committee notes).

Even if evidence is relevant, it may be excluded "if its probative value is substantially outweighed by the danger of undue prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, or needless presentation of cumulative evidence." Fed. R. Evid. 403. "District courts are given broad discretion in making a Rule 403 determination."

United States v. Bonds, 12 F.3d 540, 567 (6th Cir. 1993). "Unfair prejudice does not mean the damage to a [party]'s case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest [a] decision on an improper basis." *United States v. Newsom*, 452 F.3d 593, 603 (6th Cir. 2006) (quoting *Bonds*, 12 F.3d at 567).

Where a suit is pursued against a corporation or an entity, documents or correspondences created by its directors, employees, or agents may be construed as non-hearsay statements, depending on their context. *See* Fed. R. Evid. 801(d)(2) (describing admissions by a party-opponent); *Avondale Mills, Inc. v. Norfolk Southern Corp.*, No. 1:05-CV-2817-MBS, 2008 WL 6953956, at *4-5 (D.S.C. Feb 21, 2008) (admitting non-executive employee emails as non-hearsay in suit against a corporation); *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 454 F. Supp. 2d 966 (C.D. Cal. 2006) (same); *see also Rambus, Inc. v. Infineon Techs. AG*, 348 F. Supp. 2d 698 (E.D. Va. 2004) (admitting emails under the business records exception, Fed. R. Evid. 803(b)). For non-hearsay treatment, the party's agent or servant must have made the statement within "the scope of the agency or employment [and] . . . during the existence of the relationship." Fed. R. 801(d)(2)(D). "[T]he party seeking admission 'bears the burden of establishing the proper foundation for the admissibility of [hearsay] statements.'" *Thompson v. City of Lansing*, 410 F. App'x 922, 930 (6th Cir. 2011) (quoting *Liadis v. Sears, Roebuck & Co.*, 47 F. App'x 295, 303 (6th Cir. 2002)).

Below are the Court's rulings on these particular documents:

(a) Email from January 29, 2003 (DN 111-1): This request is DENIED. The email deals with a Japanese study on zoledronic acid, the active ingredient for Zometa. It confronts what NPC learned from the study on dosing regimes and references Zometa on several different occasions. The issues NPC cites in its motion may be addressed on cross examination should the email be introduced.

(b) Email from May 5, 2003 (DN 111-3): This request is DENIED. The email is about osteonecrosis (in the subject heading of the email) and references Zometa and Aredia. It also discusses Dr. Ruffiero's article and how it may or may not come to the attention of oncologists. Other courts having considered the same issue have allowed this email into the evidentiary record and NPC fails to provide good cause to depart from that trend. The email is relevant and it is admissible under Rule 403; NPC's objections go to its weight at trial rather than its admissibility.

(c) Email from June 20, 2003 (DN 111-6): This request is DENIED. The email, between NPC personnel, discusses thoughts on the causal links between ONJ and Zometa. Claims by NPC that it is irrelevant or overly prejudicial are disingenuous.

(d) Email from July 10, 2003 (DN 111-7): This request is DENIED. This email expressly confronts "jaw abnormalities" and "chemotherapy-induced jaw/facial [osteonecrosis]." DN 111-7 at 2. Without question, it is relevant to the matter at hand.

(e) Email from December 1, 2003 (DN 111-8): This request is DENIED. This email contains a draft of the agenda of a meeting of oncologists and surgeons who were solicited by NPC to discuss their views on ONJ, Zometa, and Aredia. The attached agenda, along with the email, constitute relevant evidence that is not overly prejudicial.

(f) Letter from January 18, 2004 (DN 111-9): This request is DEFERRED to trial. The letter is written by Sam Klein, a sales representative for NPC, and directed to an upper-level corporate director. In the letter, Klein says he has found internet postings on ONJ which may help NPC identify "enemies and allies." DN 111-9 at 2. The letter is probative of Plaintiff's allegations that NPC had a hostile view of individuals who opined on the connection between Zometa and ONJ. NPC argues the letter is inadmissible hearsay because its writer is a low-level employee, and therefore was not in the scope of his employment as required by Rule 801(d).

A factual dispute exists over the letter's creation. Plaintiff says Klein's letter was solicited by his superiors at NPC, and therefore the letter was created in the course of his employment. NPC responds the letter was gratuitous and writing such correspondences does not fall within Klein's normal responsibilities. The Court has not reviewed Klein's job description or determined whether NPC's staff solicited this letter. These matters must be resolved before a decision can be reached on the hearsay issue.

Plaintiff shall approach the bench before introducing this letter. The Court will then review the admissibility of the document with a full understanding of the facts.

(g) Email from March 12, 2004 (DN 111-10): This request is DENIED. The email, from a senior NPC official, addresses the number of ONJ cases due to Zometa as of March 12, 2004. It is relevant, probative of NPC's notice and knowledge about the disease, not significantly prejudicial, and therefore admissible.

(h) Email from May 12, 2004 (DN 111-12): This request is DENIED. The email contains and details the edits to the White Paper for Zometa regarding ONJ. Arguably, it tends to show the authors' impressions of the connection between the drug and disease prior to the White Paper's publication. It is relevant and admissible.

(i) Email from May 28, 2004 (DN 111-15): This request is DENIED. This is another email about preliminary changes to the White Paper for Zometa. For the same reasons listed in subsection (h), this email is admissible.

(j) Email from January 31, 2005 (DN 111-16): This request is GRANTED. Plaintiff has agreed to not use this email at trial.

(k) Email from June 15, 2005 (DN 111-17): This request is DEFERRED to trial. The email was created after Kyle received her treatment. Plaintiff asserts it is relevant as to NPC's prior intent and motivations. Yet, the Court is uncertain what Plaintiff means by this statement. Before introducing this exhibit, Plaintiff shall approach the bench and explain the document's relevancy.

4. Exclude photographs (DN 112)

NPC asks the Court to exclude the following pictures, should Plaintiff attempt to present them at trial: (1) photographs of persons other than Kyle with ONJ, (2) photographs of Kyle's condition or treatment, and (3) photographs of Kyle prior to her cancer diagnosis. It argues these items are irrelevant and overly prejudicial, and thus in violation of Rules 401 and 403. Neither party has provided the Court copies of these photographs.

It is easy to imagine how photographs in this case both hold the promise of aiding the jury to visualize the symptoms of this disease and the peril of shocking and prejudicing the same with graphic and emotional images. The Court encourages the parties to disclose any

questionable photographs to each other in advance of trial and reach an accord on which ones should be introduced.

In the absence of an agreement, the Court will delay ruling on this motion until trial; to act otherwise would be to improperly judge these photographs sight unseen. Certainly, some photographs of Kyle prior to her diagnosis and after she contracted ONJ will be admissible.

5. Exclude Adverse Drug Experience Reports (DN 113)

Adverse drug experience ("ADE") reports are brief statements by doctors or patients, compiled by pharmaceutical companies and then forwarded to the Food and Drug Administration ("FDA") that document "any adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a); *see Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003). A large number of ADE reports were sent to NPC relating to Zometa and ONJ. *See* Marx Expert Report ¶ 61, DN 113-2 at 15. NPC now petitions the Court to find inadmissible many of these ADE reports.

The motion seeks to exclude those reports that are not substantially similar to the events alleged in this case and those sent to NPC after Kyle started taking Zometa on October 24, 2003. It argues Plaintiff's witnesses should not be allowed to rely on specific ADE reports unless they are analogous to Kyle's medical background. NPC continues, pushing for the exclusion of references to the number of ADE reports by witnesses because the individual reports are premised on impermissible hearsay. Finally, NPC claims the ADE reports are improper evidence if they were created after Kyle began her treatment because they could not have impacted her oncologist's decision to prescribe Zometa.

The Court will divide its decision on the ADE reports into three parts: (1) their use in the

aggregate to show medical causation, (2) the introduction of specific ADE reports to show notice to NPC, (3) and how the dates of the ADE reports' creation affect their admissibility.

First, courts recognize the tenuous role ADE reports play when showing a causal link between a drug and a side effect. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001) ("Case reports make little attempt to screen out alternative causes for a patient's condition. They frequently lack analysis. And they often omit relevant facts about the patient's condition."); *Dunn*, 275 F. Supp. 2d at 682 (remarking that ADE reports "are not controlled studies", "cannot be verified through peer review", "do not include information about the patient's medical history", and "are not scientific proof of causation"). That is not to say courts endorse the general rule of exclusion for which NPC is advocating. ADE reports are proper to prove "causation in correlation" when appearing alongside other evidence *In re Levaquin Products Liab. Litig.*, No. 08-MDL-1943, No. 08-CV-5743, 2010 WL 4676973, at *4 (D. Minn. Nov. 9, 2010); *accord Bartlett v. Mutual Pharm. Co., Inc.*, No. 08-CV-358, 2010 WL 3092649, *1 (D.N.H. Aug. 2, 2010) (permitting the plaintiff's experts to rely on ADE reports to the extent they were "reasonably relied upon by experts in the particular field"); *In re Fosamax Products Liab. Litig.*, 645 F. Supp. 2d 164, 184-85 (S.D.N.Y. 2009) ("[A] large number of [ADE] reports adds greater weight to the reliability of an opinion on causation.").

The medical causation opinions of Professor Wayne A. Ray and Dr. Robert Marx, experts for Plaintiff, are based in part on the number of ADE reports that arose out of patients taking Zometa and Aredia. The issues of hearsay that are necessarily implicated with ADE reports should not preclude this testimony because experts may use otherwise inadmissible evidence to reach their opinions. Fed. R. Evid. 703. Thus, Plaintiff's experts may rely on and

make reference to the aggregate number of Zometa-related ADE reports to prove medical causation, insofar as they relied on it to form their opinions. On cross examination, NPC may address its complaints over whether the medical scenarios underlying the ADE reports are substantially similar to Kyle. Still, substantial similarity is not relevant to opinions on medical causation, so long as the expert offering the opinion did not differentiate between these ADE reports when employing his methodology. Hearsay issues will however bar experts from mentioning specific ADE reports during this portion of their testimony.

Second, ADE reports may show notice on pharmaceutical manufacturers of the drug's side effects. *See Hogan*, 2011 WL 1533467, at *13; *Bartlett*, 2010 WL 3092649, *1; *Golod v. La Roche*, 964 F. Supp. 841, 855-56 (S.D.N.Y. 1997). As case reports are of questionable reliability, courts typically impose the yard stick of "substantial similarity" to ferret out those ADE reports that could not be expected to raise the manufacturer's awareness. *Bartlett*, 2010 WL 3092649, at *1; *cf. Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 550-51 (W.D. Pa. 2003) ("[E]vidence of other injuries is not admissible unless the circumstances of the other occurrences are 'substantially similar' to those in the case at bar." (citing *Barker v. Deere and Co.*, 60 F.3d 158, 162 (3d Cir. 1995))). This Court will follow suit. If Plaintiff introduces specific ADE reports to show notice to NPC of Zometa's side effects, those reports must be substantially similar to the matter at hand. For substantial similarity, it is enough that the ADE report concern a patient suffering medical complications analogous to ONJ after taking Zometa or Aredia. *See Bartlett*, 2010 WL 3092649, *1; *Golod*, 964 F. Supp. at 855-56. Parties shall approach the bench before introducing a particular ADE report so the Court may review its background. The Court shall also issue a limiting instruction on the uses of such a report.

Third, after Kyle's tooth was extracted, subsequent ADE Reports could not have provided notice to NPC since it would have been impossible to warn her of the drug's alleged connection to ONJ. The individual reports submitted to NPC or the FDA after January of 2005 are therefore irrelevant to showing notice on NPC. Still, reports falling after this temporal dividing line are admissible to the extent they were relied upon by Plaintiff's experts to create their opinions on medical causation. They may not however be specifically referenced by the expert or introduced by the Plaintiff.

6. NPC's Knowledge and Conduct following Kyle's Zometa Treatment (DN 114)

In this motion, NPC seeks to exclude arguments and evidence surrounding its corporate activities after Kyle was prescribed and began taking Zometa on October 24, 2003. It insists its actions following this date are inapposite since the prescribing physician could only have considered Zometa's warnings prior to the start of her therapy. NPC affirms that whatever subsequent knowledge or notice it possessed about the drug's alleged connection to ONJ would be similarly irrelevant since it would have arisen after Kyle began her treatment. In the alternative, NPC petitions the Court to draw a time boundary for admission of its activities in November of 2004 (the date Kyle stopped taking Zometa) or January of 2005 (the date Kyle's tooth was removed).

Conceptually, this request makes sense; practically, it does not. No matter which date the Court chooses, documents or actions by NPC after that date could bear (or may be interpreted by a jury as bearing) on NPC's earlier knowledge about ONJ and Zometa. To ensure legitimate evidence was not excluded simply as a result of the date it was created, the Court would have to review all evidence dated after the temporal dividing line and determine whether it implicates

NPC's knowledge at an earlier stage in Zometa's development.

Such a course is improper for two reasons. First, it is unduly burdensome. The record for this matter is vast and to conduct such a review before trial would embroil the Court and parties in a pitched battle over countless documentary exhibits. Second, deciding what a jury could or could not infer from a potential exhibit would require the Court to make impermissible judgments on fact issues that are reserved strictly for the jury. *Tennant v. Peoria & P. U. Ry. Co.*, 321 U.S. 29, 35 (1944) ("It is the jury, not the court, which is the fact-finding body. It weighs the contradictory evidence and inferences, judges the credibility of witnesses, receives expert instructions, and draws the ultimate conclusion as to the facts.").

Rather than intruding into the jury's arena, the Court will deny NPC's request for a strict rule deciding the admissibility of documents between the beginning of Kyle's treatment, its termination, and her tooth extraction. NPC may instead point out the temporal discrepancies in documents and its actions during its own arguments and during the cross examination of Plaintiff's witnesses. It may also offer individualized objections to the introduction of evidence at trial if it believes the jury is incapable of drawing the necessary inferences. *See Hogan*, 2011 WL 1533467, at *11 (same conclusion). As a guide, the Court is inclined to admit evidence that was created or occurred before Kyle's tooth extraction, realizing there will be exceptions.

NPC also claims the subsequent labeling changes to Zometa and Aredia in November of 2007 and December of 2008 are impermissible evidence. Federal Rule of Evidence 407 prevents the admission of subsequent remedial measures to show "a defect in a product's design" or "a need for a warning or instruction" if such action "would have made the injury or harm less likely to occur." Fed. R. Evid. 407. Where pharmaceutical companies have altered a drug's labeling

on their own accord, courts have consistently precluded juries from considering these changes as evidence of a defect in the original warning or instruction. *E.g.*, *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 271 n. 10 (5th Cir. 2002); *DeLuryea v. Winthrop Labs., a Div. of Sterling Drug, Inc.*, 697 F.2d 222, 229 (8th Cir. 1983); *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1348 (E.D.N.Y. 1992). *But see In re Levaquin Products Liab. Litig.*, MDL No. 08-1943 (JRT), 2010 WL 4882595, at *1 (D. Minn. Nov. 24, 2010) (where FDA ordered labeling change, Rule 407 was inapplicable); *Bartlett v. Mutual Pharm. Co., Inc.*, No. 08–CV–358–JL, 2010 WL 3092649, at *2 (D.N.H. Aug. 2, 2010) (same).

The labeling changes for Zometa and Aredia in November 2007 and December 2008 fall squarely within the protections of Rule 407. DN 114-7 at 6; DN 114-8 at 9. Both mention ONJ under the subsection "Warnings and Precautions", encourage patients taking the drugs to "maintain good oral hygiene", and urge patients to "avoid invasive dental procedures if possible." DN 114-7 at 6; DN 114-8 at 9. Use of these changes during trial would subvert the policy of Rule 407 - encouraging manufactures to disseminate open and accurate information to consumers without the possibility of admitting fault.

For this reason, the changes of November 2007 and December 2008 to Zometa's and Aredia's labels may not be relied upon by the jury to show liability, a defect in a product's design, or the need for a warning or instruction. Fed. R. Evid. 407. To the extent Zometa's and Aredia's labels were altered at a time prior to November of 2007, NPC has not moved for their exclusion or attached them to the instant motion. The Court therefore does not reach the question of whether they too are impacted by Rule 407. Lastly, Plaintiff may introduce the November 2007 and December 2008 labels for appropriate purposes under Rule 407, such as

impeachment. Counsel must approach the bench before taking such actions so the Court may determine the intended evidentiary purpose of these labels.

7. Dr. Robert Marx's testimony on other ONJ patients (DN 115)

The Court previously admitted Dr. Robert Marx's expert testimony on the causal relationship between IV BP drugs and ONJ, and the steps that can be taken to prevent and treat BIONJ in the individuals receiving BP therapy. Memo. & Op. Ord. p. 27-28, DN 151 at 27-28. Marx has extensive experience treating patients with ONJ as well as researching the connection between the disorder and BP drugs like Zometa. According to the motions before the Court, Marx has seen 238 patients suffering from ONJ. NPC asks the Court to limit his testimony at trial and prevent him from addressing the medical history and treatment of the specific ONJ patients Marx has seen. It says the evidence will both confuse and prejudice the jury.

Insofar as this motion could be construed as limiting the broad strokes of Marx's expertise on ONJ, NPC's request is denied. Marx developed his opinions on ONJ - specifically its symptoms, treatment, and causes - by evaluating patients with the illness. Thus, he may testify generally about the disease, his opinion on causation, and how he developed the opinions in the context of the other patients he has treated. Marx may also speak toward the aggregate number of patients he has seen with ONJ, how that number is relevant to his opinions, and the diagnostic or medical similarities those patients share as it pertains to his expert opinions. To find otherwise would thwart the Court's earlier decision admitting him as an expert witness.

So far as Marx seeks to introduce more particularized evidence of the patients he has treated, the Court repeats the conclusion reached above for the ADE reports. Patients that have a substantially similar medical history as Kyle (those who took Zometa and subsequently

developed ONJ or analogous disorders) could bear on issues of notice to NPC and causation. Marx may speak about specific patients that are substantially similar to Kyle if they helped him form his opinion on causation, if NPC's officials examined these patients during their visit to his clinic, or if NPC was given notice of these patients' condition through an ADE report or via some other avenue.

8. Time when NPC should have warned about Zometa's risks (DN 116)

NPC asks the Court to prohibit Plaintiff from introducing evidence or arguments that it should have warned of Zometa's or Aredia's possible connection to ONJ earlier than September of 2003. The motion confronts several pieces of evidence and potential testimony.

(a) Expert testimony on adequacy of warnings: This request is DENIED. NPC asks the Court to bar arguments at trial that it should have warned patients like Kyle of Zometa's risk because Plaintiff has not provided expert testimony on the inadequacy of the drug's labeling. NPC cites no binding decisions supporting this proposition. Kentucky law does not require expert testimony in failure-to-warn cases on why the prescription drug's labeling is inadequate. *See e.g.*, *Tobin v. Astra Pharm. Products, Inc.*, 993 F.2d 528, 536 (6th Cir. 1993) (failure to warn claims cognizable in suit against pharmaceutical company with only experts on causation); *Snawder v. Cohen*, 749 F. Supp. 1473, 1481-83 (W.D. Ky. 1990) (denying the defendant's motion for summary judgment even without expert testimony supporting the plaintiff's suit for failure to warn on side effects of polio vaccine); *see also Smith v. Louis Berkman Co.*, 894 F. Supp. 1084, 1093 (W.D. Ky. 1995) (strict liability claims for design and manufacture defect were properly before the jury even without expert testimony on those subjects); *cf. Montgomery Elevator Co. v. McCullough by McCullough*, 676 S.W.2d 776, 781-82 (Ky. 1984) (describing failure-to-warn case under Kentucky law without mentioning the necessity of expert testimony).

(b) Testimony and evidence on phossy jaw: This request is DENIED. Plaintiff's experts are familiar with phossy jaw, have been deposed on the subject, and have answered questions at other trials about its connection to ONJ. The absence of an express opinion in their expert reports will not prejudice NPC. Regarding the allegation that Plaintiff's experts do not possess the appropriate background on the subject, this motion is insufficient to reach such a conclusion. NPC may cross examine Plaintiff's experts on this issue

at trial should it arise.

(c) Testimony and evidence on osteopetrosis: This request is GRANTED IN PART AND DENIED IN PART. Plaintiff does not address this objection in her response. To the extent Plaintiff's experts seek to show causation between Zometa and ONJ, or that NPC should have recognized the connection, this testimony may not be presented because it is not contained within Plaintiff experts' reports. If this information is contained in the report, then counsel needs to bring that to the Court's attention. The experts may however testify generally on their expertise with disorders of the jaw and their overall medical experience, even if it includes osteopetrosis.

(d) Testimony and evidence on the effects in animal and human studies involving different BP drugs: This request is DENIED. NPC has not offered a legitimate reason to preclude such proof at trial. Plaintiff's experts may rely on and testify about the Starck article and the Gotcher & Jee article. The issues NPC raises may be tested through vigorous cross examination.

(e) Evidence on potential cases of ONJ in Aredia's and Zometa's clinical trials: This request is DENIED. In its earlier *Daubert* ruling, the Court determined Marx was qualified to examine whether NPC had overlooked certain participants in the drug trials who developed ONJ. Memo. & Op. Ord. p. 30-32, DN 151 at 30-32. NPC's concerns in this motion may be addressed on cross examination.

9. NPC's omnibus motion in limine (DN 108)

NPC offers an omnibus motion in limine seeking an evidentiary ruling on potential statements by Plaintiff's witnesses and counsel. Each is confronted below.

(a) Out of court statements by physicians who commented on NPC's draft White Paper: This request is GRANTED IN PART AND DENIED IN PART. NPC seeks to exclude statements by independent physicians who criticized the White Paper process and the conclusions it reached. DN 109-2 at 2-7. It argues such statements are hearsay without an applicable exception. The Court agrees and will exclude the exhibits NPC has attached in support of this motion. However, the Court declines to rule on the admissibility of physician commentary to the White Paper that has not been provided for its review. NPC may raise objections to these statements at trial. *See Hogan*, 2011 WL 1533467 at *11 (same conclusion). If there are non-hearsay uses for this evidence, counsel shall approach the bench before introducing it.

(b) Testimony from Dr. Noopur Raje: This request is DENIED. Dr. Noopur

Raje is a physician who, during a medical conference, discussed how she thought NPC identified occurrences of ONJ in its clinical trials. According to her deposition, she will testify NPC under reported incidences of ONJ to the FDA during these trials. NPC suggests that her testimony is inadmissible because it is speculative and premised on hearsay.

The parties have not provided a sufficient factual basis to rule on this evidence. They have not attached the video tape of Raje's remarks at the medical conference or the entirety of her deposition to this motion. The Court will reserve its ruling until trial.

(c) Recommendations from the ONJ panel from March 16, 2005: This request is GRANTED. This meeting conducted by NPC discussed ONJ and its connection to a drug named "Reclast," which has a similar chemical makeup to Zometa. The outside consultants and NPC personnel confronted a variety of topics at the meeting, including, how to take steps for patient protection during clinical trials and how to obtain treatment recommendations.

To protect against confusion between these two drugs, their impacts, and their uses, the Court will exclude references to the ONJ panel of March 16, 2005. Reclast is not prescribed to individuals with Kyle's symptoms, and therefore the panel's discussion does not impact NPC's knowledge as to Zometa in similar patients. Thus, this particular exhibit and testimony surrounding it shall be excluded. *See Hogan*, 2011 WL 1533467 at *13 (same conclusion).

(d) Statement by Dr. Jack Gotcher at a meeting in September 2005: This request is DENIED. Dr. Jack Gotcher, an oral surgeon, made a statement to a medical panel discussing ONJ in September of 2005. He said there was evidence as far back and 1981 about a connection between BP drugs and osteonecrosis. NPC charges this statement is hearsay and inadmissible.

The Court withholds its decision until trial as there may be non-hearsay uses of the statement. Plaintiff's counsel shall approach the bench before he attempts to introduce this statement. The Court will then address its propriety while considering its context in the litigation.

(e) Sales and marketing materials that were neither seen nor relied on by Kyle and Dr. Smith: This request is DENIED. NPC asks for the exclusion of its sales or marketing materials or any advertisements regarding Zometa that Kyle or Smith did not see. The Court has not reviewed the items to which NPC is referring, and therefore cannot confirm if these advertising materials are admissible for any other purpose. The Court rejects this objection, but will permit NPC to raise it at trial.

(f) Testimony or evidence that NPC misled, deceived, or defrauded the FDA about Zometa: This request is GRANTED IN PART AND DENIED IN

PART. The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), found that the Food, Drug, and Cosmetic Act ("FDCA") preempted state-law claims of fraud on the FDA. *Id*. at 353. The Sixth Circuit has held that "permitting a fraud claim premised on false representations to the FDA . . . would conflict with well-established precedent that no implied private right of action exists under the FDCA." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); *see Bouchard*, 213 F. Supp. 2d at 812.

Still, the fact that Plaintiff intends to introduce evidence that NPC violated FDA regulations does not automatically implicate the holdings of *Buckman* and *Kemp*. State-law causes of action that track federal regulatory regimes have not been preempted by these decisions; "[t]hus, plaintiffs may use evidence - if they are able to produce it - of [a pharmaceutical company's] efforts to manipulate the [FDA] regulatory process in order to prove their negligence and strict liability claims . . . ." *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006). The state-law failure-to-warn claims may continue with evidence that NPC's actions violated FDA regulations. *E.g., Tobin v. Astra Pharm. Products, Inc.*, 993 F.2d 528, 538 (6th Cir. 1993); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 675-76 (E.D. Ky. 2006); *Bouchard*, 213 F. Supp. 2d at 812. Evidence of violations of the FDA's regulations that are introduced to support the state-law torts is admissible.

(g) Testimony or evidence that articles were ghostwritten by drug companies: This request is GRANTED. Plaintiff concedes she will not introduce any evidence on ghostwriting.

(h) Evidence concerning foreign regulatory actions or package inserts in foreign countries: This request is GRANTED IN PART AND DENIED IN PART. NPC asks that Plaintiff be prohibited from introducing package inserts distributed in foreign countries. NPC is an international company, whose headquarters is in Switzerland. Because the company transcends international boundaries, the labeling in other countries could bear on what information the company's executives were privy to and when they recognized the alleged connection between Zometa and ONJ. The Court will permit this evidence, as it may bear on NPC's knowledge and the notice it had of Zometa's side effects.

Plaintiff may not use this information to show NPC violated the FDA's regulations. Differing regulatory schemes and objectives in other nations should not impact those which governed Zometa's use in the United States. Thus, any attempt by Plaintiff to color the FDA requirements with those of other countries would be improper. The parties shall address the use of these foreign labels with more detail at trial.

(i) Phossy jaw: This motion is DENIED. As explained earlier, Plaintiff's experts may testify as to phossy jaw.

(j) Discovery disputes: This request is GRANTED. The parties have agreed not to speak about their earlier discovery disputes at trial.

(k) Characterizations of NPC's counsel: This request is GRANTED. The parties have agreed not to talk about where NPC's counsel's firm is located or where counsel resides, the practice of NPC's counsel, and the identity of NPC counsel's other clients.

(l) Reference to drug companies having an "incestuous" relationship with FDA: This request is GRANTED. Plaintiff has stipulated to refrain from using this language.

(m) Reference to Dr. Suzanne Parisian as the "Former Chief Medical Officer" of the FDA: This request is GRANTED. Parisian was *a* chief medical officer of the FDA. NPC points out that this is a title that many people have in the agency and any reference to Parisian as *the* chief medical officer is improper. The Court agrees. Plaintiff should only refer to Parisian's title in a way that will not confuse or mislead the jury.

(n) Reference to jurors' dental pain: This request is DENIED. NPC warns the Court that Plaintiff may try to have the jury evaluate Kyle's pain by harkening back to their own dental pain. The Court will confront this objection, should the need arise, at trial.

(o) Evidence of moral obligations and legal conclusions: This request is DENIED. NPC says Plaintiff will solicit testimony from its experts on NPC's "moral obligations." It also says Plaintiff will try and introduce expert testimony on legal conclusions. While this type of evidence is generally impermissible, the Court denies this request. It will reserve its ruling on these issues until trial, when and if they arise. The Court warns Plaintiff to avoid testimony on moral obligations or legal conclusions.

(p) Evidence or argument about regulatory enforcement or interactions between FDA and NPC about drugs other than Zometa: This request is GRANTED. NPC asks the Court to preclude arguments and evidence on any of its other drugs that may have drawn the scrutiny of the FDA. This information is irrelevant to the instant matter. Plaintiff brings this action to redress Kyle's alleged reaction to Zometa. Noncompliance with other pharmaceuticals would cause NPC undue prejudice and potentially confuse the jury. This decision includes, but is not limited to, statements on Reclast.

(q) References by Dr. Robert Marx about his compensation: This request is GRANTED, as the parties have agreed not to discuss Marx's compensation or lack thereof.

(r) Reference to NPC's corporate structure or fact NPC's parent is based in Switzerland: This request is GRANTED. Plaintiff has not offered a legitimate basis why this information is relevant to the current proceedings. Accordingly, the Court finds the location of NPC's principal offices inadmissible. Should the need to introduce this information arise at trial, the parties shall approach the bench.

10. Plaintiff's omnibus motion in limine (DN 118)

Plaintiff has filed her own omnibus motion in limine. Each objection is discussed below.

(a) Arguments or statements by NPC's counsel or witnesses about the approved uses of Zometa and whether it can be referred to as a "cancer drug", "wonder drug", "miracle drug", etc.: This request is DENIED. Plaintiff alleges NPC's counsel and witnesses will improperly describe Zometa's intended uses and heap unwarranted praise on the drug during the trial. Plaintiff asks the Court to restrict NPC's description of Zometa's uses and effectiveness to the list appearing on the FDA-approved label at the time Kyle stopped taking it. Plaintiff further petitions the Court to prevent NPC's counsel from using the following terms to describe Zometa: (1) "cancer drug", (2) "wonder drug", (3) "miracle drug", (4) a drug that "prolongs life", (5) a drug that "extends life", (6) a drug that "cures cancer", (7) a drug that "fights cancer", or (8) that Kyle's life was extended by Zometa. She urges this course because Zometa, technically, is not used to treat cancer. Instead, it is used to reduce skeletal related events from certain cancers that have spread to bone. According to Plaintiff, any overstatement of the drug's uses or efficacy outside the "four corners of its label" is uncalled for and violative of the FDA's regulations.

The Court is unpersuaded. In *Hogan*, the court concluded that characterizations of the drug were permitted beyond the approved uses on the label because NPC was "permitted to offer evidence of the drug's intended use and benefits to undercut proximate cause, and show . . . [the treating physician] would have prescribed Zometa . . . even if he knew" the risks of ONJ. 2011 WL 1533467 at *13. NPC should have the same opportunity to undermine proximate cause here. *See Larkin*, 153 S.W.3d at 770 (manufacturer is only liable in failure to warn cases "for damages resulting from that failure"). NPC will not be constrained to Zometa's 2004 label when describing its uses and benefits.

Nevertheless, the Court agrees that certain phrases used to describe Zometa may be inappropriate. The Court warns both parties to use caution

in their characterization of the drug. Out of context, it is difficult to say certain words should not be or could not be used. Still, terms such as "miracle" or "wonder" are questionable. The other terms targeted by this motion ("cancer drug", "prolongs life", etc.) appear admissible and a fair description of Zometa's uses and impacts.

This ruling does not address qualified experts' statements on Zometa.

(b) Comment or testimony concerning any current clinical trials or expansion of Zometa's indication: This request is DEFERRED to trial. The Court is concerned about this testimony. It could be relevant as it may bear upon elements of medical causation. *See Hogan*, 2011 WL 1533467 at *14 (same decision). However, any benefits of Zometa discovered after Kyle stopped take the drug are of questionable use since they could not have affected her decision to take it or her doctors' decision to prescribe it. Ergo, this testimony's admission depends on its context and intended use. NPC shall approach the bench before offering proof on current clinical trials or the expansion of Zometa's indication.

(c) Any comments or arguments that the absence of any FDA sanctions is proof of full and timely compliance with FDA regulations: This request is DENIED. Plaintiff intends to offer Dr. Parisian to testify that NPC's violated the FDA's regulations. Plaintiff now moves to exclude the flip side to that argument - that the FDA never sanctioned NPC for violating its regulations and the implications of this compliance.

It is unjust to allow Plaintiff to allege violations of the FDA's regulatory framework, while at the same time prohibiting NPC from explaining the absence of formal violations. Moreover, other courts have used compliance with the FDA as proof of due care by a pharmaceutical company. *Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 966 (N.D. Ill. 2001). The Court believes this evidence is both relevant and probative of NPC's defenses.

(d) Statements about other drugs: This request is GRANTED. Plaintiff seeks to exclude statements about other non-BP drugs manufactured by NPC. To avoid confusion and the introduction of extrinsic matters, the Court will prohibit the reference to other pharmaceuticals manufactured by NPC not directly linked to this litigation.

(e) References to Dr. Marx not examining Kyle: This request is GRANTED IN PART AND DENIED IN PART. In a previous trial, NPC insinuated in its closing argument that it was improper for the patient taking Zometa to not have been examined by Marx. Plaintiff moves to exclude such assertions at this trial. She claims Marx is a case-specific expert testifying as to general causation, and since there are more than 500 cases pending against NPC

alleging Zometa-related injuries, Marx did not have time to review all of these litigants individually. Plaintiff requests that if NPC makes such arguments in the case at bar, the Court permit her to question Marx why he was unable to personally treat Kyle, which would implicitly reveal the large number of cases pending against NPC.

If NPC asks or points out at trial that Marx did not examine Kyle, then Marx may explain why he did not perform the examination. NPC can certainly show that Marx did not examine Kyle before her death and argue that lessens the force of his testimony. However, Plaintiff may rehabilitate Marx by having him state why such an examination was impossible or infeasible. During any rehabilitation, Marx may testify he is an expert employed in a number of cases involving ONJ and Zometa and he did not care for Kyle due to his busy schedule. Neither Marx nor any of Plaintiff's other witnesses may reveal the number of similar lawsuits pending against NPC.

(f) Comments about too many warnings: This request is DENIED. Plaintiff pushes the Court to exclude any arguments, insinuations, or testimony that too many warning on Zometa would have diluted the effectiveness of the label's precautions. Overwarning, or warning fatigue, is a legitimate concern of manufacturers when creating labels for consumers. *E.g.*, *Forst v. Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 954-55 (E.D. Wis. 2009); *Gaeta v. Perrigo Pharm. Co.*, 562 F. Supp. 2d 1091, 1096-97 F. Supp. 2d 1091 (N.D. Cal. 2008). NPC may address these concerns as it applies to Zometa's labeling. *See Hogan*, 2011 WL 1533467 at *14 (same decision).

IV. CONCLUSION

IT IS HEREBY ORDERED:

(1) Defendant's motion in limine (DN 106) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(2) Defendant's motion in limine (DN 107) is DENIED.

(3) Defendant's motion in limine (DN 110) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(4) Defendant's motion in limine (DN 112) is DENIED.

(5) Defendant's motion in limine (DN 113) is GRANTED IN PART AND DENIED

IN PART. Testimony may be offered in a manner consistent with this opinion.

(6) Defendant's motion in limine (DN 114) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(7) Defendant's motion in limine (DN 115) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(8) Defendant's motion in limine (DN 116) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(9) Defendant's motion in limine (DN 108) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

(10) Plaintiff's motion in limine (DN 118) is GRANTED IN PART AND DENIED IN PART. Testimony may be offered in a manner consistent with this opinion.

Thomas B. Russell, Senior Judge
United States District Court

December 14, 2011