UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

RUTH DOPSON-TROUTT and
FRANK TROUTT,

Plaintiffs,

v. Case No.: 8:06-CV-1708-T-24-EAJ

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.
_____/

ORDER

This cause comes before the Court on Defendant Novartis Pharmaceuticals Corporation's Omnibus Motion *in Limine*. [Doc. 143]. Plaintiffs Ruth Dopson-Troutt and Frank Troutt filed a response in opposition. [Doc. 151]. A hearing on the motion was held after the pretrial conference on September 12, 2013.

I. BACKGROUND FACTS

Plaintiff Ruth Dopson-Troutt was diagnosed with breast cancer, which later metastasized to her hip and pelvic bones. Dr. Arthur Feldman, her oncologist, prescribed Aredia and Zometa, which are bisphosphonate drugs that are produced, sold, and marketed by Defendant Novartis Pharmaceuticals Corporation ("NPC"). From 1999 to 2005, Dopson-Troutt was infused with Aredia and then Zometa, with her last Zometa infusion occurring on May 12, 2005. Dopson-Troutt had her tooth extracted, after which she began experiencing jaw pain caused by osteonecrosis of the jaw ("ONJ").

In 2006, Dopson-Troutt and her husband brought this action against NPC, alleging that its manufacturing, labeling, marketing, selling, advertising, and distributing of Aredia and

Zometa caused their injuries and that NPC failed to, *inter alia*, adequately warn of the risk of ONJ. This action was transferred to a Multidistrict Litigation Court in the Middle District of Tennessee for consolidated pretrial proceedings with other actions brought against NPC.

In 2012, the case was remanded back to this Court. Jury trial is set to begin on October 21, 2013. Plaintiffs' remaining claims are: negligent failure to warn (count III), breach of express warranty (count IV), and loss of consortium (count VI). [Docs. 1, 138].

II. NPC'S OMNIBUS MOTION *IN LIMINE*

A. EVIDENCE OF PROXIMATE CAUSE

NPC seeks to exclude evidence regarding the possible impact of a proper and adequate warning on a non-prescribing doctor—*i.e.*, another doctor or a "reasonable doctor"—to show proximate cause, arguing that such evidence is irrelevant and inadmissible. Plaintiffs respond that proximate cause can be proven by evidence other than the prescribing doctor's testimony. Further, NPC raises a corollary issue—whether Pennsylvania applies a "heeding presumption" to pharmaceutical failure-to-warn liability cases. NPC argues that a heeding presumption does not apply; Plaintiffs argue that it does. The Court first briefly reviews Pennsylvania's proximate cause requirement in pharmaceutical drug failure-to-warn liability cases, before addressing the parties' heeding presumption and relevancy arguments.

1. Pennsylvania failure-to-warn and proximate cause

In Pennsylvania, a failure-to-warn claim in a pharmaceutical products liability case is governed by the negligence standard set forth in the Restatement (Second) of Torts § 388. *See Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996) (citing *Incollingo v. Ewing*, 282 A.2d 206, 220 n.8 (Pa. 1971)); *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa. Super. 2010). A drug manufacturer is liable only if it failed to exercise reasonable care to inform those, for whose use the

pharmaceutical is supplied, of the facts which make the product dangerous. *See Lineberger v. Wyeth,* 894 A.2d 141, 150 (Pa. Super. 2006). The intended user is the prescribing physician—not the patient. *Id*.

A prescription drug manufacturer's duty to warn therefore runs to the prescribing physician. *Id.* at 149. The rationale for this rule, known as the learned intermediary doctrine, is that it is the prescribing physician's responsibility to use his or her "own medical judgment, taking into account the data supplied from the drug manufacturer, other medical literature, and any other source available, and weighing that knowledge against the personal medical history of the patient" when deciding whether to prescribe a drug. *Id.* at 150 (citation and quotation marks omitted). Thus, if a drug manufacturer adequately warned the prescribing physician, the manufacturer is not liable for failure to warn.

However, if the warning is inadequate, a plaintiff must then establish that the inadequate warning was a proximate cause of the plaintiff's injury—*i.e.*, that a proper and adequate warning would have changed the prescribing behavior of the plaintiff's prescribing physician:

> In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.

Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. 1996) (citations and quotations omitted) ("Absent proof that a more thorough or more explicit warning would have prevented Mrs. Demmler's use of Parnate, appellants cannot establish that SmithKline's alleged failure to warn was the proximate cause of Mrs. Demmler's injuries.").

2. Heeding presumption

NPC argues that Pennsylvania does not apply a "heeding presumption"—a presumption that if an adequate warning had been provided, the user would have read and heeded the

warning—to pharmaceutical failure-to-warn cases. If a heeding presumption were to apply, NPC would have the burden to rebut the presumption of proximate cause. Plaintiffs respond that the heeding presumption does apply.

NPC cites to a line of state trial court cases refusing to apply the heeding presumption to pharmaceutical failure-to-warn cases. *See Gronniger v. American Home Products Corp.*, 2005 WL 3766685, at *5-6 (Pa. Com. Pl. Oct. 21, 2005); *Leffler v. American Home Products Corp.*, 2005 WL 2999712, at *5 (Pa. Com. Pl. Oct. 20, 2005); *Adams v. Wyeth*, 2005 WL 1528656, at *5-6 (Pa. Com. Pl. June 13, 2005). In these cases, the trial court found that Pennsylvania courts only applied the heeding presumption to certain strict liability asbestos claims. *See e.g.*, *Gronniger*, 2005 WL 3766685, at *5-6; *Leffler*, 2005 WL 2999712, at *5. The court also reasoned that applying the heeding presumption would conflict with Pennsylvania's framework for pharmaceutical failure-to-warn claims, where the manufacturer's liability is premised on a negligence theory and its duty to warn the learned intermediary.

Those state trial court cases were considered in *Fecho v. Eli Lilly and Company*, where a federal court sitting in diversity likewise held that Pennsylvania applies no heeding presumption to prescription drug failure-to-warn claims. 914 F. Supp. 2d 130, 147 (D. Mass. 2012). The *Fecho* court acknowledged that Pennsylvania asbestos cases have applied the heeding presumption. However, unlike prescription drug cases, asbestos cases are governed by a strict liability standard and involve no learned intermediary exercising independent judgment; thus, the court found that the reasoning of asbestos cases does not apply to prescription drug cases. *Id.* at 145-47 (reasoning that *Coward v. Owens-Corning Fiberglas Corporation*, 729 A.2d 614 (Pa. Super. Ct. 1999), and *Pavlik v. Lane Ltd./Tobacco Exporters Int'l*, 135 F.3d 876 (3rd Cir. 1998), do not require applying the heeding presumption in prescription drug cases).

In response, Plaintiffs assert that state trial court cases lack precedential value. However, one of the state trial court cases, *Lineberger v. Wyeth*, was affirmed on appeal of the trial court's entry of summary judgment in Wyeth's favor on the issue of proximate cause. 2005 WL 1274458, at *4-5 (Pa. Com. Pl. May 23, 2005), *aff'd* 894 A.2d 141 (Pa. Super. 2006). Although the appellate court did not expressly hold that Pennsylvania does not apply the heeding presumption to prescription drug cases, it affirmed based on its finding that the record evidence did not create a genuine issue of material fact regarding whether a different warning would have changed the doctor's prescribing methods. *Lineberger*, 894 A.2d at 149-51.

Further, in arguing that a rebuttable heeding presumption applies in this case, Plaintiffs cite without argument to asbestos strict liability cases, including the very ones considered and rejected by *Fecho* and the state court trial cases cited by NPC. The Court rejects Plaintiffs' argument and agrees with the analysis set forth in *Fecho* and the state trial court cases.

Plaintiffs also cite to *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561 (E.D. Pa. 2011), a failure-to-warn drug case. However, not only is *Wolfe* distinguishable from this case—it involved an over-the-counter, not a prescription, drug[1]—the court merely acknowledged that the "Pennsylvania Supreme Court has not ruled on whether a heeding presumption applies in a case such as this" and expressly declined to resolve the issue. *Id*. at 569.

Finally, Plaintiffs argue that *Hahn v. Richter* shows that the Pennsylvania Supreme Court has clearly applied the heeding presumption to prescription drug failure-to-warn cases. Plaintiffs' argument rests on select language quoted from the opinion—"where warning is given, the seller may reasonably assume that it will be read and heeded." *Hahn*, 673 A.2d at 891.

[1] Although the *Wolfe* defendants did not argue that "the learned intermediary doctrine should foreclose liability in" their case, the *Wolfe* court noted that "the rationale underlying the doctrine—that the prescribing physician is always the party making the 'final judgment' as to whether a patient should take a certain drug—is inapplicable to over-the-counter medicines, such as the Children's Motrin involved in this case, which [is] available to the public without prescriptions." 773 F. Supp. 2d at 570 n.4.

However, this sound bite does not show that the Pennsylvania Supreme Court applied the heeding presumption, or otherwise held that it applies to, pharmaceutical drug failure-to-warn cases. The issue in *Hahn* was not whether the heeding presumption applied; it was whether the trial court erred in determining that a pharmaceutical drug manufacturer's liability for failing to adequately warn is based on negligence, not strict liability. *Id.* at 889. In affirming, the Pennsylvania Supreme Court relied on prior pharmaceutical drug liability cases, *Incollingo v. Ewing,* 282 A.2d 206 (Pa. 1971), and *Baldino v. Castagna,* 478 A.2d 807 (Pa. 1984), and their application of comments j and k to the Restatement (Second) of Torts § 402A. *Id*. at 889-91. In this context, *Hahn* summarized comment j:

> As to what constitutes proper warnings, comment j, titled "Directions or warning," provides that a seller must warn of risks, not generally known and recognized, of which he *has or reasonably should have knowledge,* and, further, that it can be assumed that where warnings are given they will be read and heeded.

Id. at 890 (emphasis in original). *Hahn* concluded that:

> *Incollingo* and *Baldino,* as well as comments j and k, make it clear that where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability.

Id. at 891. Thus, *Hahn*'s reference to "read and heeded" was not for the purpose of applying, or affirming the application of, the heeding presumption. Rather, the reference was made in the context of summarizing comment j of § 402A to explain *Hahn*'s holding that negligence, not strict liability, governed liability in failure-to-warn claims involving prescription drugs.

Therefore, Plaintiffs' arguments regarding *Hahn*, or any other of Plaintiffs' cited cases, do not establish that Pennsylvania applies the heeding presumption. Upon review of Pennsylvania state court cases, the Court finds that heeding presumption does not apply here.

3. Testimony from witnesses other than the prescribing doctor

NPC contends Plaintiffs must prove that an inadequate warning was the proximate cause of Plaintiffs' injury with testimony from Dr. Feldman, the Pennsylvania oncologist who prescribed Aredia and Zometa to Dopson-Troutt. NPC argues that testimony from any other doctor regarding whether an adequate warning would have changed their, or a reasonable doctor's, prescribing practices is inadmissible, irrelevant, and speculative.

As support for its argument, NPC relies on *Adams v. Wyeth*, 2005 WL 1528656 (Pa. Com. Pl. June 13, 2005), where the state trial court granted Wyeth's motion for summary judgment because the plaintiff failed to establish proximate causation. In *Adams*, the plaintiff provided no testimony or record evidence from her prescribing doctor; she provided only a pharmaceutical consultant's affidavit opining that no reasonable doctor would have prescribed the drug had an adequate warning been provided. In finding that the record did not have sufficient evidence of proximate cause to proceed to trial, *Adams* stated that the pharmaceutical consultant's affidavit "[wa]s not admissible, [wa]s irrelevant and [wa]s contrary to the legal standard long established under Pennsylvania law." *Id*. at *5. Despite this language, the Court is not persuaded that *Adams* stands for the proposition that any testimony from a nonprescribing doctor regarding what a reasonable doctor would have done is inadmissible and irrelevant as a matter of Pennsylvania law. A fairer reading of *Adams* is that the court considered the pharmaceutical consultant's affidavit and, in light of the lack of any testimony from the prescribing doctor, determined that evidence of proximate cause was insufficient to go to a jury.

Although NPC couches its arguments in terms of relevance, NPC's motion boils down to its belief that Plaintiffs cannot meet their burden of showing proximate causation. However, that issue is not for the Court to decide on a motion *in limine*. The issue is whether the testimony of

other nonprescribing doctors regarding how an adequate warning would have affected them or a "reasonable doctor" is relevant and admissible. The Court finds that such testimony could be relevant. However, the Court does not know whose testimony NPC seeks to exclude, or what that testimony will be; at this time, the Court is unable to determine whether it would be admissible. NPC's motion to limine out the testimony of any doctors other than Dr. Feldman regarding whether an adequate warning would have changed their or any reasonable doctor's prescribing practices is **DENIED**.

B. PREEMPTION

Anticipating Plaintiffs' potential arguments that NPC should have made certain label changes, NPC argues that these arguments are preempted.

1. Label changes regarding dosing and duration of use

NPC seeks to exclude evidence or argument that NPC should have: (1) recommended a different dosage than the one approved by the FDA, or (2) suggested stopping Zometa after a certain number of doses or months of treatment. [Doc. 143 at 7, 9]. NPC argues that any changes to the FDA-approved dosing recommendations on the labels require prior FDA approval and are therefore preempted.

Plaintiffs respond that the FDA does not prohibit including safety information about dosing. [Doc. 151 at 11]. Plaintiffs cite to the changes-being-effected ("CBE") regulation, 21 C.F.R. 314.70(c)(2)(iii), which allows a manufacturer to change the label "[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product" without prior FDA approval.[2] Plaintiffs also cite to *Wyeth v. Levine*, 555 U.S. 555

[2] In 1999, the CBE regulation governing labeling changes was 21 C.F.R. § 314.70(c)(2). In June 22, 2004, Section 314.70 was amended, and the CBE regulation governing labeling changes was renumbered to 21 C.F.R. § 314.70(c)(6). *See* 69 Fed. Reg. 18728-01. However, the prior version, § 314.70(c)(2), is essentially the same as current version, § 314.70(c)(6)(iii).

(2009), where the United States Supreme Court held that federal law did not preempt the plaintiff's claim that the drug label inadequately warned about the risks of using the drug's administration method.

Levine involved Phenergan, a drug that could be administered intravenously by the "IV-push" method and the "IV-drip" method. The IV-push method presented a higher risk of the drug entering an artery and causing gangrene. After the *Levine* plaintiff was administered the drug by the IV-push method, Phenergan entered the plaintiff's arteries and caused gangrene in the plaintiff's arm. The plaintiff brought a failure-to-warn claim against Wyeth (the drug manufacturer) under state law, arguing that the label failed to adequately warn about the risks of the IV-push method. Wyeth argued that the plaintiff's claim was preempted by federal law.

In addressing whether federal law preempted the plaintiff's "claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration," *id*. at 565, *Levine* rejected Wyeth's argument—that Wyeth could not have unilaterally changed the label to add a stronger warning because such a change would have rendered Phenergan a new drug lacking an effective new drug application and therefore would have subjected Wyeth to liability for violating FDA regulations governing unauthorized distribution. *Levine* held that strengthening the label's warning about the administration method would not have made Phenergan a new drug; the CBE regulation permitted Wyeth to strengthen its warning about drug administration without prior FDA approval.[3] *Id.* at 570-71.

Describing Wyeth's argument as a "cramped reading of the CBE regulation," *Levine* stated that the CBE regulation "reflects the manufacturer's ultimate responsibility for its label

[3] Specifically, the CBE regulation allows a manufacturer to change a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." *Levine*, 555 U.S. at 568 (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A),(C) (2008)).

and provides a mechanism for adding safety information to the label prior to FDA approval." *Id*. at 571. Thus, "[w]hen the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." *Id*. Although the FDA could reject any changes made pursuant to the CBE regulation, *Levine* noted that Wyeth never argued that it gave the FDA an analysis concerning the risks of the administration method or that it attempted to give, but the FDA prohibited, a stronger warning. *Id.* at 572. *Levine* held that, absent clear evidence that the FDA would not have approved a label change, it was not impossible for Wyeth to abide by both federal and state law. *Id.* at 571.

As support for its contention that Plaintiffs' arguments are preempted, NPC cites to *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Company, Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). NPC contends *Mensing* "rejected the plaintiffs' argument that the manufacturer could have strengthened its labeling (*e.g.*, by proposing stronger warnings to FDA) because [of] the preemptive effect of the federal regulations." [Doc. 143 at 5].

In *Mensing*, the plaintiffs developed a disease after taking a generic drug and brought a failure-to-warn claim against the generic drug manufacturer. *Id*. at 2573. The Supreme Court held that the FDA's prohibition on changes to generic drug labels preempted state failure-to-warn claims against generic manufacturers, finding that "f]ederal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id*. at 2578. The Supreme Court also found that the CBE process available to the brand-name manufacturer in *Levine* was not available to the generic drug manufacturer in *Mensing*. *Id*. at 2581. Here, Aredia and Zometa are not generic drugs. *Mensing* is therefore inapposite to whether Plaintiffs are

prohibited from arguing that NPC should have made certain label changes regarding dosing recommendations under the CBE regulation.

NPC counters that *Mensing* is not limited to generic drug manufacturers but extends to brand-name drug manufacturers. [Doc. 143 at 8]. Citing to *Bartlett*, NPC asserts that "the Supreme Court made clear that federal law also prohibits labeling changes by brand name drug manufacturers." [*Id*.] In its argument, NPC inexplicably selects language from the *Bartlett* opinion where the Supreme Court, in summarizing the generic drug approval process, quoted 21 C.F.R. § 314.70(b)(2)(i)—a provision governing supplemental "major changes" and expressly requiring prior FDA approval—which prohibits a manufacturer from making any changes to the "qualitative or quantitative formulation of the drug product." This provision is separate from the CBE regulation at issue here.[4] Therefore, neither *Mensing* nor *Bartlett* assists NPC's argument that label changes regarding dosing recommendations are preempted in this case.

Notably, at the September 12, 2013 hearing before the Court, NPC asserted that its only reason for citing *Mensing* and *Bartlett* was to state the general proposition that a label change requiring prior FDA approval is preempted. The implication is that NPC did not cite *Mensing* and *Bartlett* to suggest that the label changes at issue here in fact require prior FDA approval (and are therefore preempted).

A review of NPC's motion *in limine* suggests otherwise. Nonetheless, taking NPC's representation at face value—*e.g.*, that *Mensing* and *Bartlett* explain that, if the FDA regulations prohibit manufacturers from making a label change without prior FDA approval, then Plaintiffs are preempted from arguing that NPC should have unilaterally made that label change—the issue

[4] To the extent NPC argues Plaintiffs' arguments relate to label changes that would constitute "major changes" requiring prior FDA approval under § 314.70(b)—rather than changes requiring no FDA approval under the CBE regulation § 314.70(c)—the Court disagrees. When describing what would be "major changes," § 314.70(b)(2)(i) expressly excludes changes described in the CBE regulation. Further, NPC has provided the Court with no authority showing that § 314.70(b) applies here—as discussed, NPC's reliance on *Bartlett* is not persuasive.

is still whether the label changes regarding the dosing recommendations at issue in this case are changes permitted under the CBE regulation (and would therefore require no prior FDA approval) or are changes falling outside the scope of the CBE regulation.

During its oral argument, NPC argued that the label changes regarding dosing are not considered CBE changes; rather, they are considered changes that would render Aredia or Zometa a new drug, requiring a new drug application and new clinical studies, under 21 C.F.R. § 310.3(h)(5), which states:

> The newness of a drug may arise by reason (among other reasons) of . . . newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

However, this argument was addressed and rejected in *Levine*. *See* 555 U.S. at 570 (changing the label to warn about IV-push administration would not have made Phenergan a new drug). NPC counters that the *Levine* label change regarding drug administration is different than the label change regarding dosage at issue. Specifically, NPC asserts that the label change in *Levine* would have simply clarified instructions regarding the existing administration method, whereas label changes in this case would not clarify the dosing instructions.

The Court rejects NPC's argument that any label change regarding dosage recommendations in this case would render Aredia or Zomedia a new drug. NPC has provided no evidence or authority showing what changes are considered a "newness of dosage" under § 310.3(h)(5), as opposed to changes that "add or strengthen an instruction about dosage" under § 317.70(c)(2)(iii). Further, given that *Levine* does not describe any particular warning that Wyeth should have included[5] and the term "clarification" appears nowhere in the opinion, NPC lacks a

[5] In fact, *Levine* stated that the jury verdict did not mandate a particular warning; rather, the jury found that there may have been several ways for Wyeth to strengthen the warning. *See* 129 S. Ct. at 1194.

basis for describing the *Levine* label change as a mere clarification of an instruction. NPC's unsupported characterization of the *Levine* label change notwithstanding, NPC has still failed to explain why label changes regarding dosing at issue here would be unlike the label changes regarding administration in *Levine*. Nor has NPC addressed the Supreme Court's finding that manufacturers are presumptively able to make label changes about dosage without FDA approval under the CBE process "[a]bsent clear evidence that the FDA would not have approved a change." *Levine*, 555 U.S. at 571. NPC has provided no evidence, let alone clear evidence, to suggest that the FDA would have rejected warnings reflecting a different dosing regimen.

Therefore, the Court will not preclude Plaintiffs from offering argument or evidence that NPC should have changed the FDA-approved label by recommending a different dosing regimen. Accordingly, NPC's motion *in limine* as to dosing is **DENIED**.

2. Label changes regarding comparisons between Aredia and Zometa

NPC seeks to prohibit Plaintiffs from arguing that the Zometa label should have stated that Aredia was safer than Zometa.

Citing 21 C.F.R. 201.57(c)(2)(iii), NPC argues that comparisons of other drugs on drug labels requires prior FDA approval, because they must be supported by "substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b)," and that no data from well-controlled studies shows that Aredia is superior to Zometa. [Doc. 143 at 7].

Plaintiffs respond that comparative studies of Zometa and Aredia in fact exist, because Aredia was used as a control during the Zometa trials and the Zometa label already describes Zometa as not inferior to Aredia. Plaintiffs argue that "[w]hen Novartis had indications that Aredia's safety profile on BRONJ was better than Zometa's . . . it had *carte blanche* through the CBE to say so on the label." [Doc. 151 at 13].

Plaintiffs fail to explain how having "indications" is equivalent to having substantial evidence from adequate and well-controlled studies—which Plaintiffs' response does not dispute is the applicable standard—showing that Aredia is safer than Zometa. However, NPC has not established that, if evidence meeting the § 314.126(b) standard existed and showed that Aredia was safer than Zometa, NPC could not have changed the label's drug comparisons under the CBE regulation (without prior FDA approval).

Without knowing what comparisons and supporting studies are at issue, the Court lacks sufficient information to make a determination. NPC's motion to prohibit argument that the Zometa label should have stated that Aredia was safer than Zometa is therefore **DENIED WITHOUT PREJUDICE**.

3. Black box warning

NPC seeks to prohibit Plaintiffs from arguing that NPC failed to adequately warn because it did not add a black box warning to the Aredia or Zometa label.[6]

NPC argues that this argument is preempted because FDA regulations prohibit NPC from unilaterally adding a black box warning without FDA's prior approval or request, and the FDA has never approved or required a black box warning for Aredia or Zometa. NPC points to several FDA statements in the Federal Register that, "to ensure the significance of boxed warnings in drug labeling, they are permitted only when specifically required by FDA." 44 Fed. Reg. 37434, 37448 (June 26, 1979).[7] Further, 21 C.F.R. § 201.57(e) provides:

[6] A "black box" warning is the strongest warning that the FDA requires. *Aaron v. Wyeth*, 2010 WL 653984, at *8 (W.D. Pa. 2010).

[7] *See also* 51 Fed. Reg. 43900-01, 43902 (Dec. 5, 1986) ("Under § 201.57(e) (21 CFR 201.57(e)), which lists specific requirements on content and format of labeling for human prescription drugs, the agency has the authority to require a 'boxed' warning on prescription drug packages for special problems, particularly those that may lead to death or serious injury. The intent of the box is to draw special attention to the warning to assure that it will be noted by the physician. The agency's policy is to use restraint in requiring warnings to be boxed because overuse of the box will ultimately lead to reducing its effect.").

> Special problems, particularity those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. . . . If a boxed warning is required, its location will be specified by the Food and Drug Administration.

Plaintiffs respond that "there is no case of the FDA striking a black box warning used by a pharmaceutical company" and therefore they are not preempted from arguing that NPC should have unilaterally added a black box warning. This does not rebut NPC's contention that the FDA regulations prohibit NPC from adding a black box warning unless the FDA specifically requests that one be added. Nor do Plaintiffs address the FDA's statements in the Federal Register cited by NPC. Plaintiffs are therefore prohibited from arguing that NPC should have unilaterally added a black box warning without prior FDA approval.

Accordingly, NPC's motion is **GRANTED**. However, the Court notes that Plaintiffs' response references NPC emails discussing the effect of a black box warning. [Doc. 151 at 6, 10]. The Court clarifies that evidence bearing on the issue of potential black box warnings may be relevant to, *inter alia*, the sorts of warnings that NPC could have added without prior FDA approval, and are therefore not necessarily inadmissible.

4. Different label formatting

NPC seeks to preclude Plaintiffs from potentially arguing that it should have formatted the Zometa labeling differently by, *inter alia*, placing the ONJ warning in different sections of the label or using a different font size or bolded text.

NPC contends such arguments are barred by 21 U.S.C. § 337(a) and threatens FDA's primary jurisdiction. Citing to *Pom Wonderful LLC v. Coca-Cola Company*, 679 F.3d 1170 (9th Cir. 2012), and 21 C.F.R. § 201.57(d), NPC contends the FDA "comprehensively regulates the formatting of prescription drug labeling" and Plaintiffs' "challenges to the FDA-approved

formatting would . . . undermine FDA's considered judgments and should be precluded." [Doc. 143 at 9-10, 11].

However, *Pom Wonderful* is not a drug label case; rather, it is a food case about a pomegranate blueberry drink label, where the Ninth Circuit discussed 21 C.F.R. § 102.33, which provides requirements for the labeling of beverages that contain fruit or vegetable juice. NPC has failed to explain how *Pom Wonderful* is applicable here. Further, NPC appears to cite to a version of the FDA regulation that was not effective at the time Dopson-Troutt used Aredia and Zometa. *Compare* 21 C.F.R. § 201.57(d) (2006) (titled "Format requirements" and providing requirements for font size and bolded text of labels) *with* 21 C.F.R. § 201.57(d) (2005) (titled "contraindications" and providing content requirements for the label's contraindications section).

The Court therefore denies NPC's motion to exclude any argument that NPC should have formatted the label differently. However, Plaintiffs state that they will not argue about FDA-disapproved font; as to this issue, NPC's motion is granted.

Accordingly, NPC's motion is **GRANTED** to the extent that Plaintiffs seek to argue that NPC should have used an FDA-disapproved font; NPC's motion is otherwise **DENIED**.

C. CORPORATE CONDUCT AFTER TOOTH EXTRACTION

NPC seeks to exclude evidence surrounding its corporate activities after Dopson-Troutt's tooth was extracted "in late 2003 or early 2004" under Rules 401-403 of the Federal Rules of Evidence. NPC argues that its subsequent knowledge or notice of ONJ after Dopson-Troutt's tooth extraction is irrelevant to the determination of liability because "there is no proximate causal connection between [its] later conduct and her injury." [Doc. 143 at 11].

Plaintiffs respond that the Court should reserve ruling on this issue, pointing to another Novartis case where the court declined to draw a strict time boundary for the admission of

evidence. The Court agrees that imposing a strict cut-off date for admissibility of evidence is impractical, because documents or actions by NPC after that date could bear on relevant issues, such as NPC's earlier knowledge about ONJ and Zometa.

The Court notes that the parties have stipulated that "documents, testimony, or other evidence concerning alleged actions or omissions by Novartis that postdate Mrs. Trouttt's last use of Zometa (May 12, 2005) are irrelevant to prove Novartis' liability and will not be offered for that purpose." [Doc. 181]. Although NPC included a footnote saying that it believed an earlier cutoff date should be imposed, NPC has failed to show why it should be the date of Dopson-Troutt's first tooth extraction, rather than the date of Dopson-Troutt's last infusion of Zometa. Accordingly, NPC's motion is **DENIED**.

III. CONCLUSION

Accordingly, it is hereby **ORDERED** that Novartis Pharmaceuticals Corporation's Omnibus Motion *in Limine* [Doc. 143] is **GRANTED IN PART AND DENIED IN PART** as provided above.

DONE AND ORDERED at Tampa, Florida, this 23rd day of September, 2013.

Susan C. Bucklew

SUSAN C. BUCKLEW
United States District Judge

Copies To: Counsel of Record and Parties