

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

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

**PLAINTIFF**

v.

**NOVARTIS PHARMACEUTICALS CORP.**

**DEFENDANT**

**MEMORANDUM OPINION AND ORDER**

Defendant has filed a motion to preclude Plaintiff's demand for punitive damages (DN 67). Plaintiff has responded (DN 92) and Defendant has replied (DN 102). This matter is now ripe for adjudication. For the reasons that follow, Defendant's motion is GRANTED IN PART.

**I. BACKGROUND**

**1. General Background**

Zometa and Aredia are two 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. Between August of 2001 and February of 2002, Zometa was approved by the Federal Drug Administration ("FDA") for the treatment of hypercalcemia of malignancy, multiple myeloma, and solid tumors. Zometa and Aredia are widely used among cancer patients suffering these types of afflictions.

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. Following the extraction of a tooth in January of 2005, Kyle developed symptoms consistent with osteonecrosis of the jaw

(“ONJ”). ONJ is a condition that results in the necrosis (or death) of jaw bone. Kyle passed away on October 1, 2008.

Plaintiff Natasha Kyle Mahaney (“Plaintiff”) now brings this action against NPC on behalf of Kyle’s estate. Plaintiff alleges Kyle developed ONJ, which was caused by Zometa. She pursues this action under the state-law theories of strict liability, negligence, and breach of implied warranties. Her principal complaint is that NPC failed to adequately warn Kyle of Zometa’s and Aredia’s dangerous side effects.

## **2. Development of Zometa and Aredia**

The following is a recitation of the facts each party relies upon to support the argument for or against punitive damages. For the most part, the common thread between these facts is that they provide insight into what NPC knew about the causal connection between BP drugs and ONJ, and when they knew it.

During the human trials of Aredia from 1992 to 2001, several patients developed symptoms that were arguably consistent with ONJ. *See* DN 93-1; DN 93-2; DN 93-3; DN 93-4; DN 93-5. In 2002, Dr. Robert Marx published a textbook where he noted the increased incidence of “exposed nonvital bone in the mandible and/or maxilla” for patients taking between 60 to 90 milligram doses of Aredia. DN 92-11 at 4. Between April and August of 2002, at least one doctor working for NPC was asked by a practicing oral surgeon if IV BP drugs, like Zometa, cause ONJ. DN 92-5 at 3. There is evidence to suggest that NPC did not squarely answer the doctor’s question or investigate the possibility. The same doctor went on to hold a seminar discussing the connection between BP drugs and ONJ, of which NPC learned in December 2002.

By December 5, 2002, NPC had received the first incident reports detailing that patients

taking IV BP drugs had symptoms consistent with ONJ. Several months later, NPC assembled a team of its staff to review and discuss the impact of the potential publication of an article describing the connection between ONJ and IV BP drugs in a magazine geared toward oral surgeons. DN 93-13 at 1-7. On June 11, 2003, Dr. Robert Marx contacted NPC's management by email, explaining he had seen 36 patients with ONJ and the only commonality between each was BP therapy. DN 93-18 at 2-3. In the months following, Dr. Marx invited officials from NPC to tour his facilities at the University of Miami School of Medicine and meet with three patients who had developed ONJ while taking IV BP drugs. DN 93-8 at 7. Although they visited, NPC's officials waited some months before altering Zometa's labels. In September of 2003, Marx published a medical alert in the Journal of Oral and Maxillofacial Surgery describing the potential connection between IV BP drugs and ONJ.

During the same month of Marx's medial alert, NPC voluntarily submitted to the FDA a supplement to Zometa's label in accordance with 21 CFR 314.70(c). DN 67-22 at 3. The following language was added to the Adverse Reactions section for Zometa's package insert:

Cases of osteonecrosis (primarily in the jaws) have been reported since market introduction. [ONJ] has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g. chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g. anemia, infection, pre-existing oral disease).

DN 67-22 at 3-4. The FDA approved the labeling changes shortly thereafter and they were made available to the public by December of 2003. Between February and September of 2004, NPC updated Zometa's label two more times, mentioning a correlation between IV BP drugs and ONJ, but never acknowledging an affirmative connection between the two. In September of 2004, NPC disseminated a clinical practice document and a letter ("Dear Doctor Letter") to some

17,000 hematologists, oral surgeons and oncologists around the country. *See* DN 67-27; DN 67-28. The documents fell short of admitting a casual relationship between IV BP drugs and ONJ, but set out ways to diagnose and minimize the risk of ONJ. The Dear Doctor Letter included the most recent labeling changes. Kyle’s oncologist received a copy of these documents in advance of her tooth extraction.

## II. STANDARD

As an initial matter, the parties dispute which standard the Court should apply in reviewing this motion to preclude punitive damages: the summary judgment standard under Federal Rule of Civil Procedure 56 or the Federal Rules of Evidence governing motions in limine. Plaintiff argues for the former while NPC contends the latter is appropriate.

Many courts reviewing whether an instruction on punitive damages is justified in a products liability action have done so in the context of summary judgment.<sup>1</sup> This is understandable, since “product-liability cases presenting punitive-damage claims require an inquiry into the defendant’s state of mind in order to prove willfulness of defendant’s conduct . . . .” 10A Fed. Prac. & Proc. Civ. § 2729.1 (3d ed.). In fact, another federal district court considering the same MDL action employed the Rule 56 standard to decide whether an instruction on punitive damages was justified. *See Fussman v. Novartis Pharm. Corp.*, No. 1:06-

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<sup>1</sup> *See e.g., Acton v. Excel Indus., Inc.*, No. 2:08-cv-315, 2009 WL 1794559, at \*5-7 (S.D. Ohio June 23, 2009) (a genuine issue in products liability action precluded granting summary judgment on request for punitive damages); *McConnell v. Cosco, Inc.*, 238 F. Supp. 2d 970, 983-84 (S.D. Ohio 2003) (jury could conclude that defendant’s behavior was conscious or a flagrant disregard of its duty, and thus summary judgment not appropriate); *Gooch v. E.I. DuPont de Nemours & Co.*, 40 F. Supp. 2d 857, 862-63 (W.D. Ky. 1998) (analyzing request for punitive damages under summary judgment); *Greco v. Ford Motor Co.*, 937 F. Supp. 810, 817 (S.D. Ind. 1996) (issue of fact meant that summary judgment on punitive damages was improper).

CV-149, 2010 WL 4273195, at \*1-2 (M.D.N.C. Oct. 25, 2010) (finding that issues of material fact precluded granting of summary judgment on punitive damages). While NPC offers precedent in support of using the rules of evidence, these decisions are either distinguishable or non-binding.<sup>2</sup>

Rather than depart from the current legal climate, the Court will construe this motion as one seeking summary judgment on punitive damages. Both parties have provided factual support for their positions and thus will not be prejudiced by this conversion. As a result, the Court will review whether “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). In so deciding, it will resolve all ambiguities and draw all reasonable inferences against NPC. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

### **III. PUNITIVE DAMAGES UNDER KENTUCKY LAW**

As Plaintiff pursues this action exclusively under state law theories of recovery, Kentucky law governs whether she is entitled to recover punitive damages against NPC. *See Rutherford v. Columbia Gas*, 575 F.3d 616, 623 (6th Cir. 2009) (where jurisdiction is exercised on diversity of parties, the substantive law of Kentucky governs the dispute). The state’s supreme court has offered the following rationale for imposing punitive damages:

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<sup>2</sup> NPC points to *Hinkel v. Navistar, Intern. Corp.*, 952 F.2d 403, \*4 (6th Cir. 1992) and *Kittel v. C-Plant Federal Credit Union*, No. 5:08-CV-00114-R, 2010 WL 2106680, at\*3-4 (W.D. Ky. May 24, 2010) as examples of courts within the Sixth Circuit have upheld the exclusion of claims for punitive damages within motions in limine. Closer review reveals that in each of these instances punitive damages were precluded by federal statute. Legal rulings such as these are a far cry from the factual questions currently before the Court.

The theory of exemplary, punitive, or vindictive damages, or ‘smart money,’ as they are sometimes called, involves a blending of the interests of society in general with those of the aggrieved individual in particular. According to the more generally accepted doctrine, such damages are allowed not because of any special merit in the injured party's case, but are awarded by way of punishment to the offender, and as a deterrent, warning, or example to defendant and others, or even, it has been said as an expression of the indignation of the jury.

*Bisset v. Goss*, 481 S.W.2d 71, 74 (Ky. 1972) (quoting 25 C.J.S. Damages § 117(1)). Since punitive damages are unbound from the actual injury suffered by the plaintiff, the total award need not be related to the compensatory damages. *Great Atl. & Pac. Tea Co. v. Smith*, 136 S.W.2d 759, 768 (Ky. 1939).

The recovery of punitive damages for products liability action under Kentucky law is governed by KRS § 411.184. See *Owens-Corning Fiberglas Corp. v. Golightly*, 976 S.W.2d 409, 411 (Ky. 1998). To receive punitive damages, the plaintiff must show the defendant acted with “oppression, fraud or malice.” KRS § 411.184(2). The terms “oppression” and “fraud” are statutorily defined. Oppression is conduct intended to subject a plaintiff to cruel and unjust hardship. *Id.* § 411.184(1)(a). Fraud is defined to be intentional misrepresentation, deceit or concealment of material fact that is known to the defendant and is concealed with the intention of causing injury to the plaintiff. *Id.* § 411.184(1)(b).

While malice was also statutorily defined within section 411.184(1), the Kentucky Supreme Court has held this particular definition unconstitutional. See *Williams v. Wilson*, 972 S.W. 2d 260 (Ky. 1998). Accordingly, courts interpreting the term “malice” under the statute have relied on the common law definition of gross negligence. See *Phelps v. Louisville Water Co.*, 103 S.W.3d 46, 51-52 (Ky. 2003). Past law “defines gross negligence as a wanton or reckless disregard for the safety of other persons.” *Kinney v. Butcher*, 131 S.W.3d 357, 359 (Ky.

Ct. App. 2004) (footnotes and quotation marks omitted). A jury is not required to make an express finding of malice, as it can be implied from a defendant's outrageous course of conduct.

*Id.*

Finally, a showing of punitive damages is only sufficient if a court finds the plaintiff has provided clear and convincing evidence of the defendant's improper behavior. KRS § 411.184(2). Under Kentucky law, clear and convincing evidence is "evidence substantially more persuasive than a preponderance of evidence but not beyond a reasonable doubt." *Fitch v. Burns*, 782 S.W.2d 618, 622 (Ky. 1999).

#### IV. DISCUSSION

##### **1. Fraud and Oppression**

Plaintiff's response to this motion does not indicate under which theory she is attempting to collect punitive damages. Nevertheless, she appears to concede that there is insufficient evidence to support a claim under section 411.184's definitions of fraud and oppression. Each definition requires intentional conduct, whether it be causing *intentional* injury to the plaintiff or *intentionally* subjecting the plaintiff to cruel and unusual hardship. *See Ventas, Inc. v. HCP, Inc.*, Nos. 09-6385, 009-6413, 2011 WL 1844093, at \*24 (6th Cir. May 17, 2011) (explaining that for punitive damages under section 411.184(1)(b), plaintiff must show intent to injure through a fraudulent scheme); *Gundaker/Jordan Am. Holdings, Inc. v. Clark*, No. 04-226-JBC, 2009 WL 2390162, at \*6 (E.D. Ky. Aug. 4, 2009) (punitive damages for oppression require a showing of intentional behavior); *Roberie v. VonBokern*, No. 2004-SC-000250-DG, 2006 WL 2454647, at \*5-6 (Ky. Aug. 24, 2006) (intentional acts of blocking public road and threatening plaintiffs sufficient for an award of punitive damages under oppression). Plaintiff has not

provided evidence that NPC, or anyone affiliated with it, consciously sought to harm Kyle or others through either fraud or oppression. Accordingly, summary judgment on these two theories for punitive damages is proper.

## **2. Wanton or Reckless Conduct**

The Court presumes Plaintiff's response pins her claim of punitive damages on wanton or reckless conduct. As explored above, an instruction on punitive damages may be presented to a jury when the negligence established is "accompanied by wanton or reckless disregard for the lives, safety, or property of others." *Ellis v. Gallatin Steel Co.*, 390 F.3d 461, 471 (6th Cir. 2004). "It is not necessary that the jury find [the defendant] acted with express malice; but rather, it is enough that [the defendant's] conduct was so outrageous that malice could be implied from the facts of the situation." *Phelps*, 103 S.W.3d at 52. "A party is entitled to have the jury instructed on the issue of punitive damages 'if there was any evidence to support an award of punitive damages.'" *Thomas v. Greenview Hosp., Inc.*, 127 S.W.3d 663, 673 (Ky. Ct. App. 2004) (citation omitted) overruled on other grounds *Lanham v. Commonwealth*, 171 S.W.3d 14 (Ky. 2005).

Buttressing this theory of recovery, Plaintiff examines in great detail the background of Zometa and Aredia as well as the rise of ONJ cases in patients taking it. The most persuasive evidence she offers showing NPC's reckless disregard for patients like Kyle transpired before Marx published his article in September of 2003: (1) the presence of five test subjects from 1992 to 2001 who allegedly developed BIONJ during the human trials; (2) the publication of Marx's textbook in 2002, warning that Aredia in certain doses created a "significant incidence of exposed non-vital bone in the mandible or maxilla"; (3) NPC's arguably lethargic reaction from



when it received the first adverse event report in December of 2002 to when the label change emerged in September of 2003; (4) internal emails during the first part of 2002 describing NPC's attempts to dissuade one doctor from publishing an article on BP drugs and ONJ; (5) the officials' visit to Marx's clinic in early June of 2003 to review his findings on ONJ, and yet still not publishing a new label until September of that year; and (6) the instruction to NPC's sales staff in August of 2003 not to raise the topic of ONJ with oncologists during sales calls. The aggregate of this evidence, along with the assurances of Kyle's medical providers that they were unaware of the Zometa's alleged risks, is the basis for Plaintiff's allegations of wanton and reckless disregard.

NPC offers another narrative, insisting instead that punitive damages are inappropriate. It points out that timely changes were made to Zometa's label after Marx's article in September of 2003, one month before Kyle began taking the drug. NPC further states the Dear Doctor Letter was sent to Kyle's oncologist in September of 2004, warning against invasive dental procedures while receiving Zometa. It was not until January of 2005 that Kyle had the tooth removed that allegedly led to her ONJ. NPC claims that even if it did not act swiftly to disseminate the information on ONJ to all of its patients, Kyle and her providers possessed the necessary data to make an informed decision.

NPC also charges that its behavior during and preceding Kyle's treatment was not wanton or with reckless disregard because there was uncertainty surrounding whether BP drugs caused ONJ. *See Robert E. Marx, Reconstruction of Defects Caused by Bisphosphonate-Induced Osteonecrosis of the Jaws*, 67 J. Oral Maxillofacial Surg. 107 (2009) ("The ill-defined terms bisphosphonate-related osteonecrosis of the jaws and bisphosphonate-associated osteonecrosis of

the jaws arose because of an uncertainty as to the cause of such osteonecrosis prior to 2007.”). It argues that since there was no concrete medical evidence linking forms of ONJ to IV BP drugs before Kyle began her treatment, NPC could not have behaved outrageously in failing to warn her.

Both Plaintiff and NPC also rely on decisions under Kentucky law, with which they analogize this matter. Plaintiff says this case most closely resembles *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93 (Ky. 2008). There, an award of punitive damages was upheld where a pharmaceutical company ignored directives by the FDA to not market a medication without warning of its risk for seizures. The company also under reported adverse event reports from patients, published misleading information for the medical community, did not follow the FDA’s protocol for sending out Dear Doctor Letters, and cautioned its sales force against mentioning the risks of the drug. *Id.* at 121-22. NPC instead compares the instant facts to *Cameron v. DaimlerChrysler Corp.*, No. Civ.A. 5:04-CV-24, 2005 WL 2674990, (E.D. Ky. Oct. 20, 2005). There, Judge Hood denied demands for punitive damages where a defectively designed automobile injured a plaintiff. In so deciding, Judge Hood noted most of the plaintiff’s allegations were based on “speculation” and the defendant’s design had not violated federal standards. *Id.* at \*8-9. NPC holds *Cameron* up to mean that where federal regulatory standards are met, punitive damages are unjustified against a manufacturer. DN 67 at 10.

On further review, the Court will reserve its decision on whether there is sufficient evidence for a punitive damage instruction for wanton or reckless conduct until after Plaintiff presents her proof at trial. The Court feels obliged to do so for several reasons. First, this inquiry principally concerns the subjective knowledge of NPC’s management and whether they

failed to act expeditiously in addressing the problems surrounding ONJ. Questions about an actor's state of mind are typically not resolved on summary judgment. *See* 10A Fed. Prac. & Proc. Civ. § 2729.1 (3d ed.). Moreover, the parties have submitted only isolated segments of the principal actors' deposition testimony. The Court is therefore left without the full picture of Zometa's development, the emergence of ONJ as a potential side effect, and NPC's subsequent reaction. To address the evidence in its entirety, the question of punitive damages is one that merits a full airing at trial.

Further granting the Court pause is the large amount of proof each litigant has offered in support of this motion. The parties have submitted more than seven hundred pages of evidence with it, and this appears to be the tip of the evidentiary iceberg. Rather than sift through the evidence at this stage, the Court prefers to confront it first hand. Such precautions will guard against an incorrect or uninformed decision.

In addition, the cases upon which the parties rely, *Cameron* and *Hyman*, are each distinguishable. First, Judge Hood found in *Cameron* that there was only speculative evidence supporting the plaintiff's claims that the defendant had acted wantonly before the automobile's sale. Here on the other hand, Plaintiff has provided more than mere conjecture, offering evidence purporting to show that NPC knew or should have known of Zometa's danger and ignored warning signs extending as far back as the clinical trials in the 1990s. *Hyman* is also dissimilar, since there the defendant pharmaceutical company went to great lengths to conceal from patients, doctors, and the FDA the prescription drug's serious side effects. While there is evidence supporting an instruction for punitive damages, NPC's behavior, as now understood by the Court, does not begin to mimic the kind displayed in *Hyman*. The Court concludes neither of

these cases are analogous, with the instant matter falling somewhere in between. To guard against a mischaracterization, the Court will wait for the full record before deciding which case this matter most resembles.

Finally, the Court will forgo deciding the current summary judgment motion because it is a close call. NPC's movements to change its label in September of 2003 were preceded by the alleged presence of BIONJ during the human trials, adverse event reports from doctors in Miami and New York, attempts by NPC's management to dissuade a doctor from publishing an article on the connection between bisphosphonates and ONJ, and instructions to its sales staff not mention the issues with Zometa and ONJ. In addition, several of Plaintiff's experts appear poised to testify the clinical trials were insufficient to test for complications like ONJ, the labeling changes in 2003 and 2004 were inadequate to warn Kyle of Zometa's dangers, and NPC's management mischaracterized the connection between Zometa and ONJ in publications subsequent to Marx's article in 2003. *See* Mem. & Op. Ord., DN 151. Although a great deal of proof underscores NPC's claims that it attempted to disseminate information about ONJ quickly and responsibly, the Court finds the evidence persuasive in foreclosing the instant motion.

## **V. CONCLUSION**

IT IS HEREBY ORDERED:

- (1) Defendant's Motion for Summary Judgment is GRANTED to the extent that Plaintiff seeks to premise the award on KRS § 411.184's definition of fraud and oppression.
- (2) The Court withholds its decision on whether an instruction to the jury for punitive damages is justified for NPC's alleged wanton or reckless conduct. The Court

will decide this matter following the close of proof by Plaintiff.

- (3) To the extent Defendant seeks to limit the evidence used during Plaintiff's case-in-chief to show its alleged wanton or reckless conduct, it may file a motion in limine prior to trial to exclude any evidence it feels would be inappropriate. However, the Court cautions Defendant on filing a motion that seeks to exclude evidence of liability or alter the instant motion's ruling.