UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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BARBARA DAVIDS

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

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MEMORANDUM OF DECISION AND ORDER

06-CV-431 (ADS)(WDW)

APPEARANCES:

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SPATT, District Judge.

On February 1, 2006, Barbara Davids ("Davids") initiated this action against Novartis Pharmaceuticals Corporation ("Novartis" or the "Defendant"), alleging that the Defendant's drug Zometa caused her to develop a condition referred to as bisphosphonate-related osteonecrosis of the jaw ("BRONJ"). In this regard, Davids brought causes of action for (1) strict products liability; (2) breach of implied warranty; and (3) negligence. On October 4, 2012, a jury trial was commenced and approximately one month later, on November 2, 2012, the jury returned a verdict finding the Defendant liable under all three causes of action and awarding Davids (1) $350,000 in compensatory damages for Davids's injuries and her pain and suffering incurred to the present date; (2) $100,000 in compensatory damages for the Davids's injuries and her pain and suffering to be incurred in the future; and (3) punitive damages in the amount of $10,000,000.

Presently before the Court are four post-trial motions. First, the Defendant moves for a mistrial based on the allegation that the jury was provided material extrinsic to the proceedings in open court, namely a dictionary definition of the word "wanton." Second, the Defendant moves to reduce the punitive damages award. Third, the Plaintiff moves to alter or amend the judgment under Federal Rule of Civil Procedure ("Fed. R. Civ. P.") 59(e), or in the alternative, Fed. R. Civ. P. 58, to include appropriate interest. Lastly, the Plaintiff moves to substitute

Davids's son, Ian Newman ("Newman"), as the Plaintiff in this case, as Davids died after the trial of this action. This last motion is unopposed.

As a preliminary matter, the Court grants the Plaintiff's unopposed motion to substitute Newman, in his capacity as Executor of Davids's estate, as the Plaintiff in this action. The caption is amended as follows:

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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IAN NEWMAN, in his capacity as Executor of the estate of BARBARA DAVIDS,

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.
----------X

The Court will now proceed to rule on the remaining motions.

I. BACKGROUND

A. Factual Background

The Court assumes the parties' familiarity with the facts in this case and will thus only recount those portions of the trial relevant to the present motions.

In August of 2001, Davids was diagnosed with Stage I breast cancer. As part of her cancer treatment, in October 8, 2003, after Davids's cancer metastasized to her bones, her oncologist, Dr. Eileen Sheehy-Milano ("Dr. Sheehy-Milano"), began infusing her with Zometa, an intravenous bisphosphonate drug manufactured by the Defendant and approved by the FDA. Zometa is prescribed to patients with, among other conditions, certain kinds of cancer that have metastasized to the bones. However, Davids alleged that Zometa caused her to develop BRONJ,

which is a certain type of osteonecrosis of the jaw ("ONJ") related to bisphosphonates. ONJ is a bone disease that causes damage or death to areas in the jaw bone.

In this regard, Davids claimed that (1) the warnings for the Zometa she used were inadequate with regard to ONJ, which the Defendant knew or reasonably should have known about at the times at issue; (2) the failure to give an adequate warning was a substantial factor in bringing about Davids's ONJ; (3) the Defendant breached its implied warranty of merchantability in that the warnings on the Zometa used by Davids were not adequate for the ordinary and regular use of the product; (4) the breach of implied warranty was a substantial factor in bringing about her injuries from ONJ; (5) the Defendant was negligent in that it failed to provide an adequate warning with respect to the relationship between Zometa and ONJ; and (6) the Defendant's negligence in failing to give an adequate warning was a substantial factor in causing the injuries to Davids. At trial, the jury found that Davids proved all of these claims and awarded Davids a total of $450,000 in compensatory damages.

The jury also found that Davids proved that the Defendant knowingly withheld or misrepresented information and warnings required to be submitted under the Food and Drug Administration's ("FDA") regulations, as to the relationship between Zometa and ONJ, and that this information and warnings were material and relevant with regard to Davids's injuries. It further found that Davids proved that the injury, loss or harm she suffered was the result of the Defendant's acts or omissions with regard to inadequate warnings and that the conduct of the Defendant was in wanton and willful disregard of Davids' rights. As such, the jury awarded the Plaintiff $10,000,000 in punitive damages.

At the trial, evidence was presented indicating that in April of 2002, Dr. Salvatore Ruggiero ("Dr. Ruggiero") contacted the Defendant concerning bisphosphonates and

osteonecrosis, but the Defendant took no action. Again, in July 0f 2002, Dr. Ruggiero contacted the Defendant and informed it that he had patients with BRONJ. In response, the Defendant sent Dr. Ruggiero a form letter, but did not conduct a formal investigation.

On December 5, 2002, an investigator for the Defendant attended a Harrigan Society presentation with regard to Dr. Ruggiero's BRONJ patients. Also in December of 2002, Dr. Cesar Migliorati, D.D.S. ("Dr. Migliorati"), sent the Defendant three cases involving BRONJ and Zometa, which it then forwarded to the FDA. In addition, Dr. Regina Landesberg ("Dr. Landesberg") sent the Defendant information about a number of cases involving patients that had half of their upper jaw bones removed apparently as a result of the Defendant's drugs. These cases were similar to the ones Dr. Ruggiero had filed with the FDA and had been trying to bring to the Defendant's attention since April of 2002. However, the Defendant ignored Dr. Landesberg's information for about a month.

Dr. Richard Kraut ("Dr. Kraut"), the Defendant's expert and Chairman of the Department of Dentistry at Montefiore Medical Center in the Bronx, also attended Dr. Ruggiero's Harrigan Society presentation. Following the presentation, Dr. Kraut returned to his hospital, where he informed the staff to look for ONJ caused by bisphosphonates. To that end, the hospital mailed a survey to approximately 450 patients who were on bisphosphonates to investigate the existence of any connection between bisphosphonates and ONJ. Ultimately, in response to BRONJ, the hospital altered its treatment protocols.

In January of 2003, Dr. Ruggiero filled out an Adverse Event for the Defendant and advised the Defendant that he had filled out MedWatch forms, which he submitted to the FDA. However, in February of 2003, the Defendant decided to delay investigating Dr. Ruggiero's cases due to concerns it had about the impact such a large number of cases would have on health

authorities. Rather, the Defendant suggested that tooth extractions and chemotherapy, rather than bisphosphonates, may be the cause of ONJ in patients taking Zometa.

Thereafter, in March of 2003, the Defendant received pages from a 2002 textbook published by Dr. Robert Marx ("Dr. Marx") which described how BRONJ was caused by another bisphosphonate called Aredia. According to Dr. Marx, in 2003, such a finding that ONJ could be related to bisphosphonates was new and unexpected. However, the Defendant did not attempt to contact Dr. Marx. Thereafter, on May 1, 2003, the Defendant found that Dr. Ruggiero's reports on the connection between Aredia and osteonecrosis were not an urgent emergency that required immediate action.

The next day, on May 2, 2003, Stefano Fratarcangeli, an employee of the Defendant, circulated to Senior Management his action steps to take in response to a forthcoming publication on BRONJ that was being prepared by Dr. Ruggiero. These action steps included preventing the publication of Dr. Ruggiero's article and providing a strong case demonstrating no cause/effect relationship between bisphosphonates like Aredia and Zometa and osteonecrosis. Also that day, another employee of the Defendant, Peter Tarassoff, reported on a plan to approach Dr. Ruggiero.

In June of 2003, the Defendant expressed concern regarding attention being brought to the apparent link between Zometa and BRONJ, because the Defendant had not proffered alternative explanations demonstrating that BRONJ could not be caused by drugs. In this regard, the Defendant wished to negate any causation between BRONJ and Zometa by implicating chemotherapy and systematic risk factors. About this time, Dr. Marx called the Defendant to discuss his cases. At the Defendant's request, Dr. Marx completed the Defendant's Adverse Event Form. He also invited the Defendant to his clinic to observe some of his BRONJ patients.

However, even after observing three of Dr. Marx's BRONJ patients, the Defendant still insisted that Zometa was not the cause of the problem. In fact, the Defendant even criticized Dr. Marx's findings when talking to an oncologist from Florida.

Dr. Marx also sent a "Letter to the Editor" concerning BRONJ that he prepared to the Defendant for edits. In response, the Defendant prepared a counterpoint, which appeared in the *Journal of Oral Maxillofacial* Surgery in October of 2003, about the same time that Dr. Marx's letter was published. In the piece, the Defendant conflated ONJ and BRONJ, despite the fact that BRONJ had been found to be a new kind of ONJ that was distinct in that it was caused by bisphosphonates, and advised prescribers not to consider making any changes in prescribing Zometa, even though a 2 mg dose of Zometa may be just as effective as a 4 mg dose. Nevertheless, Dr. Marx commended the actions taken by the Defendant to investigate the BRONJ issue.

In November of 2003, the Defendant attempted to cast doubt on the validity of Dr. Ruggiero's theories. Then, in December of 2003, the Defendant's promulgated an internal agenda in order to develop a consensus that ONJ pre-existed bisphosphonates and can be caused by a multitude of other factors. That same month the Defendant met with outside advisers on bisphosphonates and ONJ, but did not divulge to them its Internal Agenda, including its goal to gain agreement that ONJ pre-existed bisphosphonates and could be caused by many other factors.

However, oral maxillofacial surgeons informed the Defendant that previous ONJ examples were clinically different than BRONJ. Further, the Defendant's advisors told the Defendant to spread the word to dentists, oral maxillofacial surgeons and oncologists about the link between ONJ and bisphosphonates like Zometa, but the Defendant took no action. Instead,

the Defendant issued a new label that (1) did not warn of dental invasion; (2) did not indicate the relationship between the dose and response which suggested that Aredia was less likely to create BRONJ in patients than was Zometa; and (3) did not inform that Zometa was not any more effective for treating breast cancer patients than Aredia. In physician journals, the Defendant continued to advertise Zometa under the old label.

Two months later, in February of 2004, in response to a BRONJ inquiry, the Defendant emphasized the confounding factors and anecdotal nature of data suggesting an association between BRONJ and Zometa. In March of 2004, the Defendant instructed it agents to implicate other potential ONJ risk factors other than bisphosphonates as much as possible. Meanwhile, in May of 2004, Dr. Ruggiero's case series appeared in a medical journal, but not an oncology journal. As indicated above, the Defendant had attempted to persuade Dr. Ruggiero to not publish his case series.

By June of 2004, the Defendant still did not believe that a BRONJ warning should be included on Zometa's labeling, and by August of 2004, the Defendant's customer call centers still had no knowledge of Zometa causing BRONJ. Also in August 2004, Dr. Ruggiero indicated that BRONJ was not rare and that bisphosphonates were the real cause of the problem.

In its relationship with the FDA, the Defendant downplayed the number of reports connecting ONJ with Zometa. However, the FDA never cited the Defendant for violating any FDA regulations in connection with the ONJ issue nor did Davids's FDA regulatory expert, Dr. Suzanne Parisian, provide any evidence that the Defendant knew of any obligation to submit certain information to the FDA but failed to do so despite being aware of the requirement. In fact, under the applicable regulations, the information that the Defendant was required to submit to the FDA was left to the Defendant's judgment.

According to Dr. Sheehy-Milano, even if she had been aware of Zometa's link to ONJ, she still would have recommended it to Davids. Indeed, although Dr. Sheehy-Milano learned of the risk of ONJ prior to December of 2004 and knew that Davids was having problems with her jaw, she continued to prescribe Zometa to Davids for months because she believed that the risks were outweighed by Zometa's benefits.

B. Procedural History

Previously, the Court determined that the New Jersey Punitive Damages Act ("NJPDA") applied to any issue involving punitive damages in this case. See Deutsch v. Novartis Pharms. Corp., 723 F. Supp. 2d 521 (E.D.N.Y. 2010). According to the New Jersey Punitive Damages Act ("NJDPA"), a plaintiff must show with clear and convincing evidence that a defendant's acts and/or omissions were wanton or willful. The Court instructed the jury as to this standard and explained that "[a]n act or a failure to act is wantonly done if done in reckless or callous disregard of or indifference to the rights of the injured person." (2980:13–15.) The Court further explained that "[w]anton and willful disregard means a deliberate act or omission with knowledge of a high degree of probability of harm to another, and reckless indifference to the consequence of such act or omission." (2980:15–19.)

On November 2, 2012, while the jury was deliberating, the jury submitted a note to the Court asking for a "clear understanding' of the term "wanton disregard." (3009:15–18.) The Court noted that there was a clear definition of "wanton disregard" in the punitive damages charge and that it was "a very good definition of wantonly – of wanton disregard." (3009:19–22; 3010:20–21.) However, before any further action could be taken to address the jury's request, the Court received another note from the jury indicating that they had reached a verdict. (3010:23–24.)

The Defendant alleges that during the jury deliberations, members of the jury consulted a dictionary for the definition of "wanton" when deciding whether to award the Plaintiff punitive damages. In support of this allegation, the Defendant submitted an affidavit from Paulette Robinette ("Robinette"), one of the three juror consultants that the Defendant hired for this case. In her affidavit, Robinette states that on November 5, 2012, her assistant Jessica Evans ("Evans") called Juror Number One to discuss the recently completed trial and that during their discussion, Juror Number One informed Evans that during deliberations the jurors received a dictionary from the judge's assistant in response to a request for a definition of the word "wanton." However, in a later conversation with the Defendant's attorneys, Juror Number One apparently denied any extraneous information was brought to the jury.

Robinette also asserts that on November 7, 2012, her assistant Matt Milano ("Milano") called Juror Number Nine in order to speak to Juror Number Nine about the trial. Juror Number Nine allegedly told Milano that the jurors asked for a dictionary, but denied that a dictionary had been provided before a verdict was reached. Two days later, on November 9, 2012, Evans called Juror Number Eleven. According to Robinette, Juror Number Eleven, told Evans that during deliberations the jurors requested a definition of the word "wanton" and thereafter received a definition from the deputy clerk.

On December 6, 2012, Robinette claims she called Juror Number Three and that, during their discussion, Juror Number Three stated that jurors consulted a definition of the word "wanton" in a book during their deliberations. He apparently also told Robinette that he was unsure if the book was already in the jury room or was brought into the room while he was in the bathroom. Robinette asked Juror Number Three if he ever saw a dictionary in the room, to which he responded "I believe so."

II. THE DEFENDANT'S MOTION FOR A MISTRIAL OR, IN THE ALTERNATIVE, A NEW TRIAL

A. Legal Standard

The Defendant does not specify under which Federal Rule of Civil Procedure it is moving for a mistrial or, in the alternative, for a new trial. First, the Court notes that other courts have generally considered a motion for a mistrial untimely if it is not made before a jury verdict is announced. See Harrison v. Purdy Bros. Trucking Co., Inc., 312 F.3d 346, 352 (8th Cir. 2002). Rather, it appears that most courts consider such a motion as one brought under Fed. R. Civ. P. 59, provided the motion was filed within ten days of the entry of judgment. See, e.g., Zahran v. Cleary Bldg. Corp., 182 F.3d 923, 923 (7th Cir. 1999) (noting that the district court construed the plaintiff's motion for "Judgment Notwithstanding the Verdict or in the Alternate a Declaration of a Mistrial or in the Alternate a New Trial" as a Rule 59 motion for a new trial or to alter or amend the judgment); Davison v. Sun Exploration & Production Co., 857 F. 2d 988m 988 (5th Cir. 1988) (finding that where the plaintiff-appellant filed a motion for mistrial or in the alternative for a new trial, the motion was one under Fed. R. Civ. P. 59 for a new trial); Rennick v. Champion Intern. Corp., 856 F.2d 195, 195 (6th Cir. 1988) (noting that the district court construed the plaintiff's motion for a mistrial as new trial motion pursuant to Fed. R. Civ. P. 59); Mackay v. Goss, 825 F.2d 407, 407 (4th Cir. 1987) (noting that the district court construed the pro se plaintiff's motion for a mistrial as one made pursuant to Fed. R. Civ. P. 59). Cf. Ratcliff v. Rainwater, 90 F. App'x 744, 745 (declining to consider the plaintiff's postjudgment motion for a mistrial pursuant to Fed. R. Civ. P. 59, because it was not filed within ten days of the entry of judgment and instead, construing it as a Fed. R. Civ. P. 60 motion). As such, the Court shall construe the Defendant's motion as one for a new trial brought pursuant to Fed. R. Civ. P. 59.

Under Federal Rule of Civil Procedure 59 ("Fed. R. Civ. P. 59" or "Rule 59"), a court

"may, on motion, grant a new trial on all or some of the issues — and to any party — . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). "'A motion for a new trial should be granted when, in the opinion of the district court, the jury has reached a seriously erroneous result or . . . the verdict is a miscarriage of justice.'" DLC Mgmt. Corp. v. Town of Hyde Park, 163 F.3d 124, 133 (2d Cir. 1998) (quoting Song v. Ives Labor, Inc., 957 F.2d 1041, 1047 (2d Cir. 1992)). The general grounds for a new trial are that (1) the verdict is against the clear weight of the evidence; (2) the trial court was not fair; (3) substantial errors occurred in the admission or rejection of evidence or the giving or refusal of instructions to the jury; or (4) damages are excessive. 12 Moore's Federal Practice, § 59.13[1] at 59-43 (3d Ed. 2005).

In comparison to a Rule 50 motion for judgment as a matter of law, the Second Circuit has held that the standard for a Rule 59 motion in some respects is less onerous for the moving party in two ways: first, "[u]nlike judgment as a matter of law, a new trial may be granted even if there is substantial evidence supporting the jury's verdict." DLC Mgmt. Corp, 163 F.3d at 134. Second, in deciding a Rule 59 motion "a trial judge is free to weigh the evidence himself, and need not view it in the light most favorable to the verdict winner." Id. However, the granting of a new trial is an extraordinary relief, and one that "is properly granted only upon a showing of exceptional circumstances." Id. at 391.

B. As to Whether a New Trial Should be Granted

In this case, the sole basis for the Defendant's motion for a new trial is that the jury allegedly received extrajudicial material outside of the trial record by consulting a dictionary definition of the word "wanton." However, the Defendant supports this allegation of juror misconduct only with speculation and an affidavit containing first and second level hearsay.

Accordingly, the Defendant's effort to demonstrate that members of the jury may have consulted extrinsic information while determining the punitive damages award, "based on [first and] second [ ] level hearsay, is simply too thin a reed for the Court to either order a new trial or, alternatively, a post-verdict deposition and/or hearing of one or more of the jurors concerning the alleged improprieties[.]" Leibstein v. La Farge North Americ, Inc. 767 F. Supp. 2d 373, 380 (E.D.N.Y. 2011).

In this regard, the Defendant provides the Court with an affidavit from Robinette, one of its consultants. Robinette asserts that when she spoke with Juror Number Three, he suggested to her that members of the jury consulted the word "wanton" in "a book" and that, when asked whether there was a dictionary in the jury room, he answered "I believe so." The Court finds this to be unreliable, as Robinette offers merely equivocal hearsay statements. Moreover, as Robinette even admits, she asked Juror Number Three leading questions, such as whether there was a dictionary in the jury room, which calls into doubt the validity of Juror Number Three's alleged assertions. Indeed, there is no way for the Court to know whether Juror Number Three was coaxed into making these statements by a skilled juror consultant who may very well have been fishing for a specific answer on behalf of her client.

As for the other jurors discussed by Robinette in her affidavit, she did not even speak to them directly. For example, Juror Number One spoke with Robinette's assistant, Evans, and allegedly told her that the jurors received a dictionary to consult in response to their request for a definition of the word "wanton." Yet, when questioned again later by the Defendant's attorneys, he apparently denied that any extrajudicial material was brought into the jury room. Thus, not only are these statements offered by Robinette second level hearsay, but they are also contradictory. The Court cannot be expected to grant a new trial under such circumstances.

Further, Robinette's other assistant spoke with Juror Number Nine, who allegedly denied that a dictionary was ever provided to the jury. Not only is this second level hearsay, but it does not even support the Defendant's position. Lastly, Robinette states that Evans spoke with Juror Number Eleven, who told Evans that the jurors received a definition of "wanton" from the courtroom deputy. However, besides again being second level hearsay, this statement that Robinette attributes to Juror Number Eleven is vague. In fact, it is quite possible that the definition that Juror Number Eleven allegedly reports the jurors received was simply the definition from the jury instructions, which they received from the courtroom deputy. As such, without more, such as an affidavit from one of the jurors, the Court declines to grant the Defendant's motion for a new trial.

III. THE DEFENDANT'S MOTION TO REDUCE THE PUNITIVE DAMAGES AWARD

A. Legal Standard

The Defendant again does not specify under which Federal Rule of Civil Procedure it is moving to reduce the punitive damages award. However, it appears that the applicable rule is Fed. R. Civ. P. 59, under which a district court may order a new trial in whole or limited to damages, or grant remittitur by conditioning the denial of a defendant's motion for a new trial on the plaintiff accepting the reduction in damages, if the court finds that the damages awarded by the jury are excessive. See Tingley Sys. v. Norse Sys., 49 F.3d 93, 96 (2d Cir. 1995). In other words, remittitur describes "the process by which a court compels a plaintiff to choose between reduction of an excessive verdict and a new trial." Earl v. Bouchard Transp. Co., 917 F.2d 1320, 1328 (2d Cir. 1990) (quoting Shu-Tao Lin v. McDonnell Douglas Corp., 742 F.2d 45, 49 (2d Cir. 1984)).

The decision whether to grant a new trial following a jury trial under Rule 59 is "committed to the sound discretion of the trial judge." Metromedia Co. v. Fugazy, 983 F.2d 350, 363 (2d Cir. 1992). "This discretion includes overturning verdicts for excessiveness and ordering a new trial without qualification, or conditioned on the verdict winner's refusal to agree to a reduction (remittitur)." Textile Deliveries, Inc. v. Stagno, 52 F.3d 46, 49 (2d Cir. 1995). Even if substantial evidence exists to support the jury's verdict, a court has the power to grant a new trial under Rule 59. See Song v. Ives Laboratories, Inc., 957 F.2d 1041, 1047 (2d Cir. 1992).

Under federal law, "[p]unitive damages are awarded for the purpose of deterrence and retribution." Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198, 220 (E.D.N.Y. 2004) (citing State Farm Mutual Automobile Ins. Co. v. Campbell, 538 U.S. 408, 416, 123 S. Ct. 1513, 155 L. Ed. 2d 585 (2003)). However, such an award will not be disturbed unless it is "so high as to shock the judicial conscience and constitute a denial of justice." Ismail v. Cohen, 899 F.2d 183, 186 (2d Cir.1990); accord Kirsch v. Fleet St., Ltd., 148 F.3d 149, 165 (2d Cir. 1998). With respect to punitive damages, they must be "reasonable in their amount and rational in light of their purpose to punish what has occurred and to deter its repetition." Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 21 111 S. Ct. 1032, 1045, 113 L. Ed. 2d 1 (1991). In BMW of North America v. Gore, 517 U.S. 559, 574–75, 116 S. Ct. 1589, 134 L. Ed. 2d 809 (1996), the Supreme Court identified three "guideposts" for determining whether a punitive damage award is excessive: (1) the degree of reprehensibility; (2) the disparity between the harm or potential harm and the punitive damages award namely, the proportion or ratio of punitive damages to compensatory damages; and (3) the difference between the remedy and the civil penalties authorized or imposed in comparable cases.

In addition, in this case, New Jersey law applies to the issue of punitive damages. New Jersey caps punitive damages at the greater of $350,000 or five times the compensatory damages award. N.J. Stat. Ann. § 2A:15–5.14(b). Further, under the NJPDA,

> [p]unitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence including gross negligence.

N.J. Stat. Ann. § 2A:15–5.12(a). Also, the NJPDA sets forth the following non-exclusive list of factors that the factfinder must consider in determining whether to award punitive damages:

> (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct;
> (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct;
> (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and
> (4) The duration of the conduct or any concealment of it by the defendant.

Id. at (b)(1)-(b)(4).

Moreover, where, as here, a case involves a product or label approved by FDA, the punitive damages provision of the New Jersey Products Liability Act ("NJPLA") provides drug and device manufacturers immunity from punitive damages if the drug or device which caused the harm was approved by the FDA, "or is generally recognized as safe and effective pursuant to conditions established by the [FDA] and applicable regulations, including packaging and labeling regulations." Id. at § 2A:58C–5(c). However, under the statute, this immunity is unavailable and punitive damages are permitted "where the product manufacturer knowingly

withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question." Id.

B. As to Whether the Punitive Damages Award Should be Reduced

At the outset, the Court acknowledges that both the Plaintiff and the Defendant appear to agree that the $10 million punitive damages award is excessive under the NJPDA and must at least be reduced to $2,250,000, excluding interest, or, in other words, five times the compensatory damages award of $450,000. Therefore, the issue presented to the Court is whether the punitive damages award should be even further reduced below $2.25 million. In this regard, the Defendant argues that a $2.25 million punitive damages award is still excessive both under the Due Process Clause of the Constitution and under the NJPDA. Conversely, the Plaintiff contends that a $2.25 million punitive damages award is not excessive under the NJPDA and that the NJPDA's punitive damages cap comports with all Constitutional requirements.

The Court begins it analysis by first considering whether awarding a $2.25 million punitive damages in this case violates the Due Process Clause of the United States Constitution. To that end, the Court reviews the award for excessiveness under three Gore guideposts listed above – that is, (1) the degree of reprehensibility; (2) the disparity between the harm or potential harm and the punitive damages award namely, the proportion or ratio of punitive damages to compensatory damages; and (3) the difference between the remedy and the civil penalties authorized or imposed in comparable cases. 517 U.S. at 574–75.

As to the reprehensibility of the Defendant's conduct, this Court "should consider (1) whether the harm caused was physical, as opposed to merely economic; (2) whether the tortious conduct evinced an indifference to, or a reckless disregard of, the health and safety of

others; (3) whether the target of the conduct had financial vulnerability; (4) whether the tortious conduct involved repeated actions, or was an isolated incident; and (5) whether the harm was the result of intentional malice, trickery, or deceit, or was a mere accident." Fagan, 356 F. Supp. 2d at 220 (citing Campbell, 538 U.S. at 416). Notably, reprehensibility is "[p]erhaps the most important indicium of the reasonableness of a punitive damages award." Gore, 517 U.S. at 575.

In this case, the Court finds that sufficient evidence was presented at trial to support a finding that the Defendant's conduct was reprehensible. First, the harm to the Plaintiff was physical, as it caused her to suffer BRONJ, as well as interfered with the treatment of her cancer. Second, the Defendant's decision to not more vigorously investigate and warn the medical community about the possibility of its drugs causing BRONJ shows a reckless disregard of the health and safety of others. Indeed, several doctors, including Dr. Marx, Dr. Landesberg, Dr. Migliorati and Dr. Ruggiero provided the Defendant with warnings about the causal connection between Zometa and BRONJ, and yet the Defendant irresponsibly delayed in taking action to alert the medical community and patients of this danger.

Third, the target of the conduct was the Plaintiff and other cancer patients. Presumably, many of these patients, as individual consumers undergoing costly cancer treatment, would be financially vulnerable. Fourth, the Defendant's conduct was not an isolated incident, but instead constituted repeated actions of either ignoring or undercutting warnings about a BRONJ-Zometa association. Finally, the conduct was not accidental, but rather intentional, on the part of the Defendant, presumably to protect their brand.

Of importance, the Fourth Circuit in Fussman v. Novartis Pharmaceuticals Corp., 509 F. App'x 214 (4th Cir. 2013), recently issued a decision in a similar case involving the Defendant. In Fussman, the plaintiff brought a failure to warn action against the Defendant, alleging that

Aredia and Zometa caused her to develop ONJ. Following a jury verdict award in favor of the plaintiff in the amount of $1,258,083.19, including $861,000 in punitive damages, the Defendant moved, in relevant part, for judgment as a matter of law on punitive damages. The Defendant argued "(1) that the evidence of its misconduct suggests negligence, not willful or wanton conduct as required under North Carolina law to support a punitive damages award and (2) that evidence of its suppression of medical information regarding ONJ cannot support a punitive damages award because Fussman failed to demonstrate a causal nexus between [the Defendant's] acts and her harm." Id. at 224.

However, the Fourth Circuit disagreed with the Plaintiff, explaining as follows:

> First, Fussman presented evidence showing that [the Defendant's] high-ranking officials knew about the drugs' side effects and subverted medical inquiries into such effects. This evidence provided a sufficient foundation for the jury to determine that Novartis's actions were willful, not simply negligent. And second, Fussman presented evidence sufficient to support a determination that [the Defendant's] acts proximately caused her ONJ. Fussman's deposition testimony, taken before her death and presented at trial, indicated that she would not have taken Aredia and Zometa if she had known the drugs' risks. Indeed, evidence presented at trial indicated that Fussman stopped taking the drugs once she knew their hazards. Moreover, although Dr. Shaw testified that she would have continued Fussman's treatments even if she had known that ONJ was a possibility, the jury could have determined from other evidence that Dr. Shaw would have modified various aspects of Fussman's treatment had she been adequately warned of the drugs' perils.

Id.

The Court is faced with very similar circumstances in the present case and therefore, finds the Fourth Circuit's well-reasoned opinion to be particularly applicable. As in Fussman, the Plaintiff in this case presented evidence demonstrating that the Defendant's high-ranking employees were aware of Zometa's side effects but ignored this dangerous issue and interfered

with investigations attempting to warn of this association, such as (1) attempting to undermine Dr. Ruggiero's findings on BRONJ and preventing the publication of his article addressing BRONJ; (2) criticizing Dr. Mar's findings to an oncologist from Florida and preparing a counterpoint to Dr. Marx's Letter to the Editor concerning BRONJ; and (3) instructing its agents to implicate other potential ONJ risk factors other than bisphosphonates as much as possible despite the evidence it had received revealing a connection between Zometa and ONJ. Moreover, the Defendant here, as in Fussman, tries to undermine the causal nexus between the Defendant's acts and the Plaintiff's harm by emphasizing that the Plaintiff's doctor, Dr. Sheehy-Milano, would have still continued to prescribe Zometa even if she had known about the side effects. Nevertheless, the Court agrees with the Fourth Circuit that the jury could have relied on other evidence to find that Dr. Sheehy-Milano would have modified the Plaintiff's treatment if she was aware of Zometa's risks. Accordingly, the Court finds that the Defendant's conduct sufficiently reprehensible to support a $2.25 million punitive damages award.

However, the Court's inquiry does not end there. Next, the Court must consider the disparity between the harm or potential harm and the punitive damages award namely, the proportion or ratio of punitive damages to compensatory damages. In this case, if $2.25 million punitive damages is awarded, the ratio of punitive damages to compensatory damages will be five to one. This is in line with what the New Jersey legislature, through the NJPDA, has deemed to be acceptable. Nevertheless, when considering the relationship between harm and punitive damages, the Second Circuit has instructed as follows:

> When the compensable injury was small but the reprehensibility of the defendant's conduct was great, the ratio of a reasonable punitive award to the small compensatory award will necessarily be very high. If in such cases significant punitive awards are not available, because of the high ratio in relation to the compensatory award, a plaintiff will often be unable to sue as

> attorneys would be unable to collect a reasonable fee through a contingency arrangement. Thus, in cases of very small injury but very reprehensible conduct, the appropriate ratios can be very high. . . . In such cases, the large size of the ratio has no necessary bearing on the appropriateness of the amount of punitive damages.
>
> On the other hand, when the harm to the plaintiff is substantial, and sufficient to result in a compensatory award large enough to finance a reasonable contingent attorneys' fee, even a single digit ratio can mean a high punitive award approaching $1 million. Thus, . . . [w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit[.]

Payne v. Jones, 711 F.3d 85, 102 (2d Cir. 2012) (citations and internal quotation marks omitted). Therefore, while the NJPDA may permit a punitive damages award of five times the amount of the compensatory damages, the Court finds that the Second Circuit's reasoning still must be applied to determine whether such a ratio is appropriate in this particular case.

Here, because the compensatory damages awarded to the Plaintiff in this case were already considerable, a five to one ratio results in a punitive damages award exceeding two million dollars. As the Second Circuit suggests, "given the substantial amount of the compensatory award, the punitive award five times greater appears high." Id. at 102. In addition, the Court notes that a $2.25 million punitive damages award is significantly more than that which was awarded in Fussman. Indeed, following North Carolina's punitive damages laws, the Fourth Circuit upheld the district court's award of only $861,000 in punitive damages, which was three times the amount of compensatory damages of $287,000, which was less than the compensatory damages awarded in this case. Fussman, 509 F. App'x at 217, 225. As such, given the large compensatory damages awarded in this case, the Court finds that requires a further reduction in the punitive damages award from five times the compensatory damages to twice the compensatory damages, thus reducing the punitive damages award to $900,000.

Lastly, the Court considers the difference between the remedy and the civil penalties authorized or imposed in comparable cases. As an initial matter, the Court notes that this factor is "accorded less weight in the reasonableness analysis than the first two guideposts." Kemp v. American Tel. & Tel. Co., 393 F. 3d 1354, 1364 (11th Cir. 2004) (citing Campbell, 538 U.S. at 428).

Nevertheless, the Defendant stresses that the civil penalties provided under the FDA enforcement scheme are significantly less than a $2.25 million punitive damages award and, thus, argues for a punitive damages award of $225,000. Pursuant to 21 U.S.C. § 333(a)(2), the Defendant could be fined up to $10,000 for violating 21 U.S.C. § 331(b), which prohibits the "misbranding of any [ ] drug . . . in interstate commerce." However, the Defendant overlooks that each misleading label was a separate violation of federal law. Therefore, in the aggregate, the Defendant would face considerable civil penalties. In light of this, the Court finds that a $900,000 punitive damages award does not violate the Due Process Clause of the United State Constitution.

Although the Court has determined that a $900,000 punitive damages award is not unconstitutional, the punitive damages award must also comport with the NJPDA. As stated above, "[p]unitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were . . . accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J. Stat. Ann. § 2A:15–5.12(a). Moreover, the following factors must be considered: "(1) the likelihood, at the relevant time, that serious harm would arise from the defendant's conduct; (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from

the defendant's conduct; (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and (4) The duration of the conduct or any concealment of it by the defendant." Id. at (b)(1)-(b)(4).

Of note, these factors are "similar" to the Gore guideposts. See Saffos v. Avaya Inc., 16 A.3d 1076, 1090, 419 N.J. Super. 244, 267 (N.J. App. Div. 2011). In this regard, as the Court indicated when discussing the reprehensibility guidepost, the Defendant was warned by several doctors of the connection between Zometa and BRONJ and yet decided to not only ignore these warnings, but to even undermine them. By doing so, the Defendant knew or should have known that its conduct could have resulted in at least some patients who were prescribed Zometa developing BRONJ, an undeniably serious harm. Moreover, even when the Defendant learned of more cases of BRONJ, it did not alter its course of conduct. Indeed, from 2002 to 2004, the Defendant engaged in conduct apparently intended to subvert any attempts to warn the medical community and patients of the potential dangerous side effects of Zometa.

Accordingly, the Court holds that in this case, a reduced punitive damages award of $900,000 is valid under the NJDPA. The Court believes that an award in this amount adequately serves the "deterrence and retribution" purpose of punitive damages. Saffos, 16 A.3d at 1091 (citing Campbell, 538 at 416).

IV. THE PLAINTIFF'S MOTION TO APPLY THE APPRORIATE INTEREST TO THE JUDGMENT

A. Legal Standard

Lastly, the Plaintiff moves to apply appropriate interest to the judgment pursuant to Fed. R. Civ. P. 59(e), or in the alternative, Fed. R. Civ. P. 58. Rule 59(e) governs motions to "alter or amend a judgment." Courts have recognized three major grounds justifying reconsideration pursuant to Rule 59(e): "an intervening change of controlling law, the availability of new

evidence, or the need to correct a clear error or prevent manifest injustice." Virgin Atlantic Airways, Ltd. v. Nat'l Mediation Bd., 956 F.2d 1245, 1255 (2d Cir.1992) (citations and internal quotation marks omitted). "The standard for granting such a motion is strict, and reconsideration will generally be denied unless the moving party can point to controlling decisions or data that the court overlooked—matters, in other words, that might reasonably be expected to alter the conclusion reached by the court." Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir.1995); see also Rafter v. Liddle, 288 F. App'x 768, 769 (2d Cir. 2008). To invoke Rule 59(e) to alter or amend a judgment, the moving party must move "no later than 28 days after entry of judgment." Fed. R. Civ. P. 59(e); see also Local Civil Rule 6.3.

As to Fed. R. Civ. P. 58, this rule requires that "[e]very judgment and amended judgment [ ] be set out in a separate document[.]" However, "a separate document is not required for an order disposing of a motion . . . to alter or amend the judgment, under Rule 59[.]" Fed. R. Civ. P. 58(a)(4).

B. As to Whether New York Law or New Jersey Law Applies to the Issue of Prejudgment Interest

According to the Plaintiff, New Jersey law should apply prejudgment interest to the punitive damages portion of the Plaintiff's award. The Plaintiff claims that under New Jersey law, prejudgment interest applies to judgments from the date of filing the claim, which in this case, would be February 1, 2006. In contrast, the Defendant argues that New York law applies, under which pre-verdict damages apparently are not available.

However, it appears to the Court that New Jersey law does not permit prejudgment interest on punitive damages awards. See Belmont Condominium Ass'n, Inc. v. Geibel, __ A.3d __, 2013 WL 3387636, at * 22–23 (N. J. App. Div. 2013) ("Prejudgment interest on punitive damages should not be permitted") (quoting Zalewski v. Gallagher, 275 A.2d 1195, 150 N.J.

Super. 360 (N.J. App. Div. 1977)) (internal brackets omitted); Baker v. National State Bank, 801 A.2d 1158, 1167, 1177, 353 N.J. Super. 145, 159, 176 (N.J. App. Div. 2002) (awarding prejudgment interest on the compensatory or actual damages, but only awarding postjudgment interest on the punitive damages award); Ward v. Zelikovsky, 623 A.2d 285, 295, 263 N.J. Super 497, 513 (N.J. App. Div. 1993), reversed on other grounds 136 N.J. 516, 643 A.2d 972 (1994) ("It is settled that prejudgment interest may not be allowed on an award of punitive damages.") (collecting cases). This is because under New Jersey law,

> [p]rejudgment interest is assessed on tort judgments because the defendant has had the use, and the plaintiff has not, of moneys *which the judgment finds was the damage plaintiff suffered*. It is thus clearly implied that interest on the *loss* suffered by a plaintiff as a result of defendant's tortious conduct is what was contemplated[.] . . . Interest is not punitive . . . ; here it is compensatory, to indemnify the claimant for the loss of what the moneys due him would presumably have earned if payment had not been delayed . . .
>
> An award of punitive damages, by its own terms, is punitive in nature and purpose and the award of interest thereon no less so. Such damages do not compensate plaintiff for a loss sustained; their purpose is to punish a defendant for wrongful, malicious conduct and as a deterrent to such conduct in the future.

Belmont, 2013 WL 3387636, at *22–23 (quoting Belinski v. Goodman, 354 A.2d 92, 96, 139 N.J. Super. 351, 260 (App. Div. 1976)).

As such, the Court denies the Plaintiff's motion to apply prejudgment interest to the punitive damages award.

V. CONCLUSION

For the foregoing reasons, it is hereby

ORDERED, that the Plaintiff's motion to substitute Barbara Davids's son, Ian Newman, in his capacity as Executor of Davids's estate, as the Plaintiff in this action is granted. The amended caption is set forth above; and it is further

ORDERED, that the Defendant's motion for a mistrial is denied; and it is further

ORDERED, that the Defendant's motion to reduce the punitive damages is granted in part and denied in part. The Court reduces the punitive damages award to $900,000. The Plaintiff may file with the Clerk of the Court within thirty days of the date of this Order an acceptance of remittitur as to the punitive damages. In the event that the Plaintiff does not file an acceptance of the remittitur within thirty days of the date of this Order, a new trial solely on the issue of punitive damages will commence on a date to be set by the Court. However, if there is consent to the remittitur, the Clerk is directed to enter judgment in favor of the Plaintiff against the Defendant for damages in the total sum of $1,350,000; and it is further

ORDERED, that the Plaintiff's motion to apply prejudgment interest or the punitive damages award is denied.

SO ORDERED.
Dated: Central Islip, New York
October 9, 2013

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge