UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

NANCY GUENTHER and DONALD GUENTHER,

Plaintiffs,

v. **Case No: 6:08-cv-456-Orl-31DAB**

NOVARTIS PHARMACEUTICAL CORPORATION,

Defendant.

ORDER

This matter comes before the Court without a hearing on the Motion for Judgment Notwithstanding the Verdict (Doc. 307) filed by the Defendant, Novartis Pharmaceutical Corporation ("Novartis"), the response in opposition (Doc. 308) filed by the Plaintiffs, and the reply (Doc. 311) filed by Novartis.

I. Background

Novartis produces and markets Zometa, a prescription drug. Nancy Guenther[1] took Zometa and developed osteonecrosis of the jaw (henceforth, "ONJ"). In March 2008, she sued Novartis, alleging that Zometa had caused the ONJ and that Novartis had failed to provide a proper warning of the risk of such harm. The matter went to trial in September 2013, with Guenther proceeding under two theories: negligent failure to warn and strict liability failure to warn.

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[1] Donald Guenther was also a plaintiff in this case, but his claim is not at issue in this motion. Accordingly, for the sake of simplicity, the remainder of this order will refer to Nancy Guenther as "Guenther" or "Plaintiff".

After nine days of trial and roughly seven hours of deliberations, the jury returned with an inconsistent verdict. In essence, the jury found that the warning provided by Novartis was not adequate for purposes of the negligent failure to warn claim but that it was adequate for purposes of the strict liability failure to warn claim. The Court explained to the jury that their findings as to the adequacy of the warning had to be consistent, one way or the other. After receiving this explanation, the jury resumed deliberations. After ten additional minutes of deliberation, the jury returned with an amended verdict, finding Novartis liable under both theories. The jury awarded Nancy Guenther $300,000 for "actual medical expenses" and $1,000,000 for "physical and emotional pain and mental anguish."[2]

By way of the instant motion, Novartis seeks judgment in its favor notwithstanding the verdict; failing that, Novartis requests a new trial, or remittitur.

II. Standards

A. Judgment as a Matter of Law

If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may resolve the issue against the party and grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue. Fed.R.Civ.P. 50(a)(1). When deciding a motion for judgment as a matter of law, the court is required to review the evidence and draw all reasonable inferences in favor of the non-moving party. *Akouri v. State of Florida Dep't of Transp.*, 408 F.3d 1338, 1343 (11th Cir. 2005). A motion for judgment as a matter of law can be made at any time before the case is submitted to the jury. Fed.R.Civ.P. 50(a)(2). The motion

[2] The jury had awarded Nancy Guenther the same amounts in its original verdict.

must specify the judgment sought and the law and facts that entitle the movant to the judgment. *Id.*

If the court does not grant the Rule 50(a) motion, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. Fed.R.Civ.P. 50(b). No more than 28 days after the entry of judgment – or if the motion addresses a jury issue not decided by the verdict, no later than 28 days after the jury was discharged – the movant may file a renewed motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59. Fed.R.Civ.P. 50(b). If a court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed. Fed.R.Civ.P. 50(c).

B. New Trial and Remittitur

The court may, on motion, grant a new trial on all or some of the issues, and to any party. Fed.R.Civ.P. 59(a)(1). After a jury trial, the court may do so for any reason for which a new trial has heretofore been granted in an action at law in federal court; after a nonjury trial, the court may do so for any reason for which a rehearing has heretofore been granted in a suit in equity in federal court. *Id.*

A motion under Rule 59 is an appropriate means to challenge the size of the verdict. 11 Charles Alan Wright et al, Fed. Prac. & Proc. Civ. § 2807 (3d ed. 2013). A grossly excessive award may warrant a finding that the jury's verdict was swayed by passion and prejudice and thus require a new trial. *Goldstein v. Manhattan Industries, Inc.*, 758 F.2d 1435, 1447 (11th Cir. 1985). However, a new trial should be ordered only where the verdict is so excessive as to shock the conscience of the court. *Id.* In general, the appropriate remedy where the jury's award

exceeds the amount established by the evidence is a remittitur order, conditioning denial of the motion for a new trial on the plaintiff's acceptance of a damages award at the outer limit of the proof. *Id.*

III. Analysis[3]

A. JNOV

Novartis offers two arguments in favor of its Rule 50(b) motion. Its first argument is that Guenther failed to present sufficient expert testimony to establish that Zometa's labels provided inadequate warnings. However, there was evidence presented by Guenther's experts Dr. Marx and by Dr. Parisian that Novartis knew or should have known of the association between Zometa and ONJ prior to September 2003, when it altered the Zometa labels to first include information about ONJ. There was also evidence presented showing that, internally, Novartis employees were much less equivocal about the association between Zometa and ONJ than the company was indicating publicly (both via the label and via other communications with the medical community). Sufficient evidence was produced to justify a finding that Zometa's label did not provide an adequate warning of the risk of ONJ during the time when Guenther was taking the drug.

Novartis also argues that, even assuming that the warnings provided were inadequate, Guenther failed to prove that the inadequacy of the warnings was the proximate cause of her jaw injury. Novartis bases this argument primarily on the fact that neither of the physicians who prescribed Zometa to Guenther testified that they would have declined to prescribe it had they known, at the time, of the association between that drug and ONJ. According to Novartis, Florida

[3] Guenther argues that Novartis waived several arguments it now makes by failing to raise them appropriately in earlier motions, but the Court finds that Novartis preserved those issues.

law requires such a showing to establish probable cause in a failure to warn prescription drug case. But this is not an accurate statement of Florida law.

Novartis pulls a quote from a Second Circuit decision, *In re Fosamax Products Liability Litigation*, 707 F.3d 189, 193 (2d Cir. 2013), which states that, under Florida law, a plaintiff in a failure to warn case "must … show that a treating physician would have recommended that the patient cease taking the drug if a different, adequate warning had been provided." But in that case, which was decided on summary judgment, the only causation evidence provided by the plaintiff came from a physician who did not know that the plaintiff had been taking Fosamax during the relevant time frame.[4] In other words, the testifying physician had not been in a position to respond in any way to a "different, adequate warning." Because of this, the *Fosamax* court did not need to address the question of whether such a warning might have prevented plaintiff's injury by, for example, being passed along to the plaintiff by the physician and leading her to reject the physician's recommendation. To the extent that the *Fosamax* court states that the *only* way for a plaintiff to prevail is to show that a different warning would have led the physician to not prescribe the drug, the statement is dicta.

Novartis also points to *Hoffman-La Roche, Inc. v. Mason*, 27 So. 3d 75 (Fla. 1st DCA 2009), as standing for this proposition. In that case, the plaintiff contended that the product's label failed to properly warn of a link between Accutane and a medical condition he developed, but his prescribing physician testified to the contrary – *i.e.*, that he understood the label as warning of that connection. *Id.* at 77. In addition, there was no evidence presented that the prescribing physician would have done anything differently, even if the label had contained all of the

[4] More specifically, the appellate court ruled that the district court should have disregarded the physician's testimony that he knew the plaintiff was taking Fosamax during that period, because he had previously given testimony stating just the opposite. *Id.* at 193-95.

information suggested by the plaintiff's expert. *Id.* As in *Fosamax*, the question of whether a different warning could have prevented the plaintiff's injury in some manner other than by changing the physician's decision to prescribe – *e.g.*, by prompting the physician to pass along a more detailed warning, or to reduce the dosage -- was not before the *Mason* court.

Even *Payne v. Novartis Pharmaceuticals Corp.* 2013 WL4779571 (E.D.Tenn. Sept. 6, 2013), which Novartis relied in this motion and in its Rule 50(a) motion, contradicts the position Novartis now advances. The opinion in *Payne* – which was decided under Tennessee law -- cites approvingly to *Smith v. Pfizer, Inc.*, 688 F.Supp.2d 735 (M.D.Tenn. 2010), a pharmaceutical products liability case in which the defendant drug manufacturers sought summary judgment based on the learned intermediary doctrine. In that case, a patient had committed suicide after taking a prescription drug called Neurontin; the patient's widow argued that Neurontin's label should have warned of a link between the drug and depression and suicidal ideation. *Id.* at 738.

In considering the manufacturers' motion for summary judgment, the *Smith* court noted that there was no evidence that additional warnings would have caused the prescribing physician to have avoided prescribing Neurontin to the patient. *Id.* at 746. If Novartis's assessment of the law was correct, this should have required the *Smith* court to rule in favor of the drug manufacturers. Instead, the *Smith* court examined the issue of whether a different warning might have prevented the harm by affecting the actions of the patient. The prescribing physician and his nurse had testified that they would have passed any additional warnings along to the patient, and there was testimony that the patient had expressed misgivings about Neurontin's side effects while taking the drug. *Id.* at 746. The court found that this was enough to avoid summary judgment: "From this evidence, the jury could reasonably conclude that Smith would have stopped taking

Neurontin if [the prescribing physician] had told him in March 2004 that he should be alert to the possibility of increased depression or suicidality." *Id.*

The *Payne* court also contradicts Novartis's assessment of the law. In describing *Smith,* the *Payne* court recounted the foregoing and stated: "*Smith* is consistent with the Court's understanding of Tennessee law. … The doctor's warning would have put the patient in the position of preventing the injury (suicide)." *Payne* at *8. The *Payne* court reached a different result than the court in *Smith*, finding that a different warning from Payne's physician's would not have affected Payne's behavior.[5] *Id.*at 9. Nonetheless, in making that finding, the *Payne* court implicitly rejected Novartis's argument that the only decision that matters for purposes of proximate cause is that of the prescribing physician.

Finally, Novartis takes issue with what it calls Guenther's "dose and duration" arguments. First, Novartis argues Guenther failed to present expert testimony that her injury could have been prevented if she had received a lower dosage or fewer doses of Zometa. However, there was testimony from Dr. Marx that reducing dosages of a drug reduces its side effects, as well as testimony about the cumulative effect of Zometa based on its 11-year half life, and his effort to encourage Novartis to determine whether a lower recommended dosage of Zometa could accomplish the same beneficial results. (Doc. 295-6 at 38-39). There was also evidence that Guenther did not exhibit any symptoms of ONJ until after she had been given numerous doses of

[5] The physician in *Payne* testified that he had changed his procedures since learning of a link between bisphosphonates and ONJ; however, the change – a recommendation that patients have a dental exam before beginning bisphosphonates – would not have helped Payne, as her ONJ developed spontaneously. *Id.* at 9. The court rejected as "entirely speculative" Payne's testimony that she would not have taken bisphosphonates at all if warned of a possible link between bisphosphonates and ONJ. *Id.* at 9 n.9. Novartis argues that similar testimony by the plaintiff in this case should also be dismissed as speculative. However, the undersigned finds that the credibility of the plaintiff on this point is properly decided by the jury rather than the court.

Zometa; from this, the jury could have concluded that Guenther would not have developed ONJ at all if she had ceased taking the drug at an earlier time.

Novartis also reiterates its previously rejected arguments that it was legally forbidden from altering Zometa's label to warn that a patient's risk of suffering ONJ increased with more doses of the drug. *See* Doc. 193. The Court sees no reason to revisit its earlier ruling on this point.

B. New Trial

Novartis makes several arguments in favor of a new trial. First, it argues that it was error for the court to allow this case to go to the jury on two different but overlapping legal theories – *i.e.*, negligent failure to warn and strict liability failure to warn. Novartis does not allege that either theory was improperly put before the jury; rather, Novartis argues that allowing the jury to consider both theories was improper.

Admittedly, the jury's initial verdict was inconsistent, finding in favor of the Plaintiff on the negligent failure to warn claim and in favor of Novartis on the strict liability claim. (Doc. 281). This initially inconsistent verdict was rendered consistent within minutes. Nonetheless, Novartis argues that it was prejudiced because "if the Court had instructed the jurors on only one claim (and given them a verdict sheet with only one claim), they could have found for [Novartis] on that claim." (Doc. 305 at 19). The Court does not find this argument to be persuasive. After being told that it was effectively deciding only one claim, the jury quickly found against Novartis.

Novartis also complains that the jury instructions erroneously instructed the jurors that they could find in favor of the plaintiff without linking any failure to warn to Guenther's prescribing physicians. Novartis is referring to this Court's determination that Florida courts, if called upon to decide the question, would determine that a drug manufacturer's duty to warn runs not just to prescribing physicians, but also to other health care providers in a position to reduce the

risk of harm to the patient. Novartis has not shown that this determination was erroneous. Even assuming *arguendo* that the instruction was erroneous, Novartis has not even described a plausible scenario, given the facts of this case, in which the instruction could have lead this particular jury to reach an erroneous conclusion.

Similarly, Novartis complains that some of its promotional material was admitted into evidence even though Guenther's prescribing physicians had not seen or relied upon the material. Even assuming the promotional material should not have been admitted, Novartis offers no explanation as to how that material could have led the jury to an incorrect result.

Prior to trial, the Court determined that Florida's four-year statute of limitations applied to Guenther's claims rather than Georgia's two-year statute. (Doc. 168). Novartis argues that it is entitled to a new trial to allow the jury to consider whether Guenther knew or should have known more than two years prior to bringing suit that her injury was caused by Zometa. However, Novartis has not presented the Court with any information or argument that would warrant overturning its previous determination as to the appropriate statute of limitations.

C. Remittitur

The jury awarded Guenther medical expenses in the amount of $300,000. As Novartis correctly points out, at most Guenther presented evidence of $105,330 of past medical expenses. Guenther argues that her medical condition is permanent, and that this permanence would justify a jury award to offset medical expenses she can be expected to incur in the future. However, as no evidence was presented on this score, any award by the jury for future medical expenses would have been sheer speculation, and it cannot stand.

Citing *Nationwide Mut. Fire Ins.* Co. v. Harrell, 53 So. 3d 1084, 1087-88 (Fla. 1st DCA 2010), Guenther argues that Novartis waived its objection to an award of future medical expenses

by failing to do so prior to the jury being discharged. However, the rule cited by Novartis applies to inconsistent verdicts; in this case, the problem is that an award of future medical expenses lacks evidentiary support, not that it is inconsistent with the remainder of the verdict. There was no waiver.

Florida Statute 768.76, titled "Collateral Sources of Indemnity," provides in pertinent part that

> In any action to which this part applies in which liability is admitted or is determined by the trier of fact and in which damages are awarded to compensate the claimant for losses sustained, the court shall reduce the amount of such award by the total of all amounts which have been paid for the benefit of the claimant, or which are otherwise available to the claimant, from all collateral sources; however, there shall be no reduction for collateral sources for which a subrogation or reimbursement right exists.

Pursuant to this section, Novartis seeks to have the medical expenses award reduced by $93,430,74 for collateral source payments and contractual discounts[6] in the following amounts: $61,181.10 for Zometa infusions, $30,969.88 for Dr. Marx's care, and $1,279.76 for Dr. Schaumberg's care. In support of its request, Novartis provides billing records and insurance reimbursement records showing collateral source payments and reductions.

Guenther does not dispute the figures provided by Novartis. Instead, Guenther argues that to obtain a setoff under Fla. Stat. § 768.76, Novartis was required to show that the entity providing these benefits to her had no right of subrogation or reimbursement. However, on its face the statute does not impose such an obligation on the non-prevailing party. Moreover, Guenther has not cited any precedent for imposing such a burden on a party in Novartis's position or offered a

[6] The Florida Supreme Court has held that contractual "write-offs" by medical providers are collateral sources for purposes of Fla. Stat. §768.76 and should therefore be set off against damages awards. *Goble v. Frohman*, 901 So. 2d 830, 832 (Fla. 2005).

compelling argument for doing so. Therefore, the Court finds that it was incumbent upon Guenther to prove that the entity from which she received these benefits had some right of subrogation or reimbursement. Guenther has not provided any such evidence. Accordingly, the Court finds that it is obligated by Fla. Stat. § 768.76 to reduce Guenther's award of actual medical expenses by $93,430.74. Subtracting this sum from the amount supported by the evidence at trial -- $105,330 -- leaves $11,899.26.

IV. Conclusion

In consideration of the foregoing, it is hereby **ORDERED** that the Motion for Judgment Notwithstanding the Verdict (Doc. 307) is **GRANTED IN PART AND DENIED IN PART** as set forth above. On or before February 28, 2014, Guenther shall file a notice as to whether she will accept a remittitur of the actual medical expenses award to $11,899.26. If she declines to accept the remittitur, Novartis will be granted a new trial as to damages, only. In all other respects, the motion is **DENIED**.

DONE and **ORDERED** in Chambers, Orlando, Florida on February 20, 2014.

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record
Unrepresented Party