UNITED STATES DISTRICT COURT
DISTRICT OF PUERTO RICO

HELEN RIVERA-ADAMS, et al.,

Plaintiffs,

v.

WYETH,

Defendant.

Civil No. 03-1713 (JAF)

OPINION AND ORDER

Plaintiffs brought the present diversity action against Defendant, pursuant to Commonwealth tort law, 31 L.P.R.A. § 5141 (1993), alleging that the drug Prempro caused Plaintiff Helen Rivera-Adams ("Rivera") to develop breast cancer. After a jury trial spanning over three weeks, the jury returned a verdict in favor of Plaintiffs on December 30, 2010. (Docket No. 215.) This court reserved judgment on the Defendant's Rule 50 motion at the close of Plaintiffs' case-in-chief, awaiting the jury verdict. (Docket No. 197.) Defendant renews, under Federal Rule of Civil Procedure 50(b), its motion for judgment as a matter of law on all issues, and it seeks, in the alternative, a new trial. (Docket No. 220.) Plaintiffs oppose, arguing that the jury could have inferred from the evidence presented that Prempro played a causal role in Rivera's breast cancer. (Docket No. 225.)

I.

Standard: Judgment as a Matter of Law and New Trial

A. Judgment as a Matter of Law

We may grant judgment as a matter of law "only if reasonable persons could not have reached the conclusion that the jury embraced." Granfield v. CSX Transp., Inc., 597 F.3d 474, 482 (1st Cir. 2010) (quoting Sánchez v. P.R. Oil Co., 37 F.3d 712, 716 (1st Cir. 1994)). In deciding a motion under Rule 50 of the Federal Rules of Civil Procedure, we "examin[e] the evidence presented to the jury, and all reasonable inferences that may be drawn from such evidence, in the light most favorable to the jury verdict." Id. (internal quotation marks omitted). A court may not overturn a jury verdict "unless there was only one conclusion the jury could have reached." Crowley v. L.L. Bean, Inc., 303 F.3d 387, 393 (1st Cir. 2002) (citation omitted).

In its Rule 50 analysis, the court may "not take into account the credibility of witnesses, resolve evidentiary conflicts, nor ponder the weight of the evidence introduced at trial." Peguero-Moronta v. Santiago, 464 F.3d 29, 45 (1st Cir. 2006) (citing Figueroa-Torres v. Toledo-Davila, 232 F.3d 270, 273 (1st Cir. 2000)). Although we draw all reasonable inferences from the record in favor of the non-movant, "the non-moving party with the burden of proof must . . . present more than a mere scintilla of evidence and may not rely on conjecture or speculation." Barkan v. Dunkin' Donuts, Inc., 627 F.3d 34, 39 (1st Cir. 2010) (internal citations and quotation marks omitted)).

B. New Trial

"The district court should grant a motion for a new trial only if the outcome is against the clear weight of the evidence such that upholding the verdict will result in a miscarriage of justice." Correia v. Feeney, 620 F.3d 9, 11 (1st Cir. Mass. 2010) (citing Goulet v. New Penn

Motor Express, Inc., 512 F.3d 34, 44 (1st Cir. 2008)) (internal quotation marks omitted). In our analysis for a motion for a new trial under Rule 59 of the Federal Rules of Civil Procedure, we "may weigh the evidence but [be] mindful that 'a jury's verdict on the facts should only be overturned in the most compelling circumstances." Goulet, 512 F.3d at 44 (quoting Velazquez v. Figueroa-Gomez, 996 F.2d 425, 427 (1st Cir. 1993)).[1]

II.

Discussion

I have reflected upon the verdict. The evidence as seen under the Rule 50 standards reviewed above shows that there were some troublesome exhibits generated by Wyeth that would allow a reasonable juror to conclude that the company was aware of certain risks involved with Prempro therapy. These exhibits also confirm that tactical and marketing compromises were made at the time the product was placed on the market, affecting how the public is made aware of the risk/benefit balancing factors for Prempro use.

With respect to the admissibility of Plaintiffs' expert testimony, we remind the Defendant that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. 579, 596 (1993). I find that reasonable jurors may have given weight to Wyeth's internal discussions which, coupled with the testimony of Plaintiffs' witnesses, could have led them to reasonably conclude that the risk factors were downplayed by Wyeth at the time the label and product were first produced. I also find that after rigorous cross-examination by Defendants, the jury could have found, based on the expert

[1] Unlike a motion for judgment as a matter of law, we need not consider "the evidence in the light most favorable to the verdict winner." Jennings v. Jones, 587 F.3d 430, 438 (1st Cir. 2009).

testimony, that Prempro played some role in speeding the development of Rivera's breast cancer, even if it was a minor one as a promoter.

A. Judgment as a Matter of Law

Defendant offers several familiar grounds to support its motion seeking judgment as a matter of law, arguing that: (1) Plaintiffs failed to show general causation; (2) Plaintiffs failed to show specific causation; (3) the suit was not timely under the applicable statute of limitations; (4) Rivera had no valid refill prescription for Prempro; (5) Wyeth did adequately warn and test Prempro with respect to the risk of breast cancer. For the reasons discussed below, we reject Defendant's arguments.

1. General Causation

Rule 702 of the Federal Rules of Evidence governs the admission of expert testimony.[2] To be admissible, expert testimony must consist of "(1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592 (1993). A trial judge's gatekeeping function requires this court to ensure that an "expert's testimony 'both [(1)] rests on a reliable foundation and [(2)] is relevant to the task at hand.'" United States v. Pena, 586 F.3d 105, 110 (1st Cir. 2009) (citing Daubert, 509 U.S. at 597).

Defendant argues that Plaintiffs' general causation experts, Dr. Austin and Dr. Colditz, failed to support their opinions with scientific data, and pointed to no study that could demonstrate Prempro can cause cancer after a nineteen-month course of treatment.

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[2] Rule 702 "requires that expert testimony be (1) based upon sufficient facts or data, (2) the product of reliable principles and methods, and (3) that the witness apply the principles and methods reliably to the facts of the case." Pages-Ramirez v. Ramirez-Gonzalez, 605 F.3d 109, 113 (1st Cir. 2010) (citing Fed. R. Evid. 702).

Dr. Austin and Dr. Colditz did identify studies, and did address the results of the large Women's Health Initiative ("WHI") study, offering their explanation of the factors that differentiated Rivera's case. While we understand that randomized clinical trials like the WHI may be the gold standard for scientific evidence, Plaintiffs' experts did not completely disregard the WHI, and were rigorously cross-examined on the matter. "When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury."). United States v. Vargas, 471 F.3d 255, 264 (1st Cir. 2006) (quoting Int'l Adhesive Coating, Co. v. Bolton Emerson Int'l, 851 F.2d 540, 545 (1st Cir. 1988)). The jury carefully considered and heard the cross-examination of Plaintiffs' causation experts, as well as the conflicting testimony of Defendant's experts.

2. Specific Causation

Defendant claims that Dr. Wertheimer, Plaintiffs' expert, presented insufficient evidence to support his opinion that Prempro caused or contributed to Rivera's breast cancer. Defendant also argues that, as Dr. Wertheimer has no training or publication experience in the field of epidemiology, this court should reject his opinion on causation. (Docket No. 220-1 at 10.) Experts need not be "blue-ribbon practitioners." United States v. Mahone, 453 F.3d 68, 71 (1st Cir. 2006). We have already rejected Defendant's challenges to Dr. Wertheimer's qualifications—both during the pretrial phase and after voir dire—and found that he had the relevant training, experience, and skill to testify in breast cancer surgery and related "overlapping areas" of expertise. (Docket No. 192 at 41.) We also addressed the Daubert challenges to Wertheimer's methodology underlying his specific causation opinion at the pretrial stage. While we might have been less than impressed with his testimony, we decline to usurp the role of the jury as factfinder. See Currier v. United Techs. Corp., 393 F.3d 246,

252 (1st Cir. 2004) (approving "district court's decision to view this weakness in [an expert's] analysis as a matter of weight rather than admissibility and thus properly a subject of argument and jury judgment").

3. Statute of Limitations

On the issue of the statute of limitations, the evidence, seen in the light most favorable to Plaintiffs, shows that there was a good probability that Rivera became aware of the tortfeasor's responsibility after the WHI study was made public; thus, the jury reasonably concluded that the Plaintiffs' suit fell within the statutory period to bring suit.

4. Problematic Prescription Records

Regarding Rivera's medical history, the testimony and evidence was sufficiently in conflict that the jury could have found that she never officially filled her prescription or the refills, or that she destroyed the prescription records as Defendant alleges. I find that the jury gave due consideration to the evidence, and their finding certainly does not create a miscarriage of justice.[3]

5. Adequacy of Warning and Testing

Defendant reprises another old argument, alleging that Plaintiffs failed to show that the warning label accompanying Prempro was inadequate. The evidence presented at trial, viewed in the light most favorable to Plaintiffs, could have supported the jury's conclusion that the warning did not adequately alert physicians of the risk of breast cancer. The evidence at trial

[3] The jury may well have found that she did indeed self-medicate or served herself the Prempro, and that she never officially filled the prescription or the refills, or that she destroyed the prescription records as Defendant alleges. Here, we look at the amount of her compensation, and the lack of compensation awarded to the rest of the plaintiffs, as evidence that the jury may have found her guilty of some sort of comparative negligence by reason of her handling of the medication and her prescription records. While it is true that no party asked for an instruction on comparative negligence, I suspect the jury considered it, and discounted the award amount accordingly.

could reasonably support a finding that Plaintiffs met the elements of a failure-to-warn claim under Puerto Rico law, namely that "(1) the manufacturer knew, or should have known the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; and (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." Cruz-Vargas v. R.J. Reynolds Tobacco, Co., 348 F.3d 271, 276 (1st Cir. 2001) (citations and internal quotation marks omitted). Defendant makes much of the fact that Dr. Parisian hinted at, but was unable to identify, an industry standard of care to show what a reasonable company would have done when testing and marketing Prempro. For Plaintiffs' strict-liability claim, however, Dr. Parisian's testimony would not have been relevant with respect to a standard of care but, instead, proved relevant on the issue of whether the "the manufacturer knew, or should have known the risk inherent in the product," as opposed to illustrating an industry standard of care. Cruz-Vargas v. R.J. Reynolds Tobacco, Co., 348 F.3d 271, 276 (1st Cir. 2001) (internal quotation marks omitted) (citing Aponte Rivera v. Sears Roebuck de P.R., Inc., 144 D.P.R. 830 (1998)).

B. New Trial

Defendant seeks a new trial, pointing to a formidable list of alleged errors and injustices. We discuss each in turn, and find none of Defendant's arguments merit a new trial under the Rule 59 standard outlined above in Part I.B.

1. Problems with Rivera's Testimony

First, Defendant alleges that Rivera testified falsely that her physician renewed her prescription, despite the lack of any record or documentation of such a visit. However, Defendant's counsel fully explored the alleged inconsistencies during cross-examination in

Rivera's testimony. The jury heard and understood the conflict with the medical records, and was entitled to decide the weight and credibility of Rivera's testimony.

Furthermore, Defendant asserts that it was unfairly surprised by Rivera's trial testimony that she transferred her prescription records, even though Defendant was aware of the lack of prescription records after the close of discovery months ago. An unfair surprise of new testimony or evidence must be "inconsistent with substantial justice in order to justify a grant of a new trial." Perez-Perez v. Popular Leasing Rental, Inc., 993 F.2d 281, 287 (1st Cir. 1993) (quotation marks omitted).

Here, Rivera's testimony cannot be construed as inconsistent with substantial justice; Defendant had ample opportunity to cross-examine Rivera on the matter, and present its arguments to the jury regarding the alleged spoilage. See Incase Inc. v. Timex Corp., 488 F.3d 46, 59 (1st Cir. 2007) (rejecting alleged unfair surprise as inconsistent with substantial justice when surprised party had "ample opportunity" to cross-examine witness and present their arguments).

2. Clear Weight of the Evidence

Defendant offers familiar arguments in its allegations that the jury's decision was against the clear weight of the evidence. First, Defendant alleges that Rivera took Prempro without a prescription—an argument that we have already rejected. Second, it argues that Plaintiffs' causation theories presented at trial were too weak to support a finding that Prempro played a causal role in Rivera's cancer. We reject this argument, as discussed above in Part II.A., and below in Part II.B.3. Finally, Defendant argues that Rivera had known before taking Prempro of the risks of breast cancer. While we might not agree with all of the jury's conclusions, reasonable minds could differ as to the evidence presented at trial, and the jury undoubtedly

heard and considered Rivera's conflicting prior testimony as to whether or not she had read the label.[4] We decline to substitute our opinion for that of the jury.

3. Alleged Improper Admission of Expert Testimony

Defendant first argues once again that this court admitted unreliable expert testimony of causation. As discussed earlier in Part II.A., we reject this argument and find that Defendant's objections "even while cloaked as objections to his qualifications under Rule 702, are actually objections about the weight of the evidence." Granfield, 597 F.3d 474, 487 (1st Cir. 2010). Voir dire and cross-examination gave Defendant's counsel extensive opportunities to highlight flaws in expert testimony for the jury.

Defendant also claims that Plaintiffs' counsel impermissibly raised the opinions of Dr. Michaels, an expert retained by plaintiffs but not allowed to testify as to causation at trial. (Docket No. 221 at 12.) During the cross-examination of Defendant's expert, Dr. Palazzo, Plaintiffs' counsel questioned the witness about whether he disagreed with statements in the report of Dr. Michaels, which was not a part of the record. (Id.) Dr. Palazzo had, in fact, employed the opinions of Dr. Michaels in his own expert report, and expressed his disagreement with the opinions and, thus, we see no problem with the Plaintiffs' limited return to the opinions of Dr. Michaels during cross-examination. See Fed. R. Evid. 705 ("The expert may in any event be required to disclose the underlying facts or data on cross-examination.").

Next, Defendant argues that Plaintiffs impermissibly read the hearsay statements of Dr. Peter Bach during cross-examination. Defendant did not timely object to the reading of

[4] Even if the jury decided that she had read the label, they might have still found the label warning inadequate. After all, the jury did specifically conclude that Wyeth failed to adequately warn Rivera's prescribing doctor of the risk of breast cancer. (Docket No. 215 at 1.)

Dr. Bach's statement during cross-examination and, thus, we employ the plain-error standard for this hearsay challenge. Fed. R. Evid. 103; see also Miranda v. Empresas Diaz Masso, Inc., 699 F. Supp. 2d 413, 430 (D.P.R. 2010) (citing United States v. Vazquez-Botet, 532 F.3d 37, 54 (1st Cir. 2008).). To satisfy the plain-error standard, Defendant must show there was "(1) an error, (2) that is plain, and (3) that affects substantial rights, and that the error seriously impaired the fairness, integrity, or public reputation of judicial proceedings." United States v. Brown, 510 F.3d 57, 72 (1st Cir. 2007) (citations and internal quotation marks omitted). We see no "plain errors affecting substantial rights" here. Fed. R. Evid. 103(d).

During the cross-examination of Dr. Palazzo, Plaintiffs' counsel read aloud certain statements of a Dr. Bach, who was not an expert in this case. (Docket No. 232 at 133–35.) The statements were made in relation to a 2010 report following up on the results of the Women's Health Initiative ("WHI") study, a large randomized clinical trial to track the effects of hormone replacement therapy. The witness expressed his disagreement with the statements, and explained that they were taken out of context, and the questioning segued into the topic of Dr. Palazzo's habits in analyzing studies and articles. The statements were not offered for the truth of the matter asserted, nor did the witness refer to a non-witness expert to corroborate his opinion. "[W]hile regarding the course followed as undesirable practice, we would not find it to be plain error affecting substantial rights where no one objected to it." Suarez Matos v. Ashford Presbyterian Community Hosp., 4 F.3d 47, 50 (1st Cir. 1993).

Next, Defendant argues that Plaintiffs' counsel introduced alleged hearsay opinions of Dr. Cummings during the cross-examination of Dr. Laidley.[5] Again, Defendant failed to object

[5] Defendant's counsel had questioned Dr. Romaguera—the prior expert witness—about the work of Dr. Cummings.

to the introduction of the material on any grounds except foundation. (Docket 231 at 256.) Additionally, the witness was familiar with the work of Dr. Cummings, and the questions were not posed to present the evidence as truth of the matter asserted, but were raised during a cross-examination discussion of the material relied upon by the expert in preparation of her expert report and opinions. Moreover, this court actually put a stop to the line of questioning after Plaintiffs' counsel began to delve into material unfamiliar to the witness.[6]

Furthermore, Defendant complains that Plaintiffs' counsel presented alleged hearsay material from the International Agency for Research on Cancer—specifically, that Prempro was included on a list of known carcinogens—during the cross-examination of Dr. Palazzo. (Docket No. 221 at 14.) The statement arose in the context of the expert witness' work for the World Health Organization, and Dr. Palazzo voiced his disagreement. (Docket No. 232 at 75–76.) The statement was not offered for the truth of the matter asserted. Again, Defendant did not object on hearsay grounds at the time, and we find no plain error in allowing the question during cross- examination.

Defendant also argues that it was prejudiced when Dr. Wertheimer allegedly offered the unfounded hearsay statement that Prempro had caused 200,000 breast cancers. (Docket No. 221 at 14–15.) Defendant objected on relevance, Rule 403, and hearsay grounds at the time of the statement. (Docket No. 192 at 154.)

The admission of Dr. Wertheimer's statement, even if based on hearsay or lacking in foundation and erroneously admitted, would fall into the category of "errors or defects which

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[6] "Unless you establish a foundation that [the witness] is aware of these things, I cannot let it go, because then it will be basically you telling us what they said and leave it at that. So we can't do that." (Docket No. 231 at 256.)

do not affect the substantial rights of the parties." 28 U.S.C. § 2111. After seeing all of the evidence offered in this case, we conclude that the jury had ample evidence—apart from this statement—of Prempro's ability to promote cancer. Additionally, during jury instructions, this court explicitly reminded jurors that "[d]amages are not meant to compensate populations of women or other people not before the Court as parties to this case," and that each plaintiff must have proved they suffered individual damages. (Docket No. 233 at 167.) For days upon days, the jury heard about large studies regarding Prempro and breast cancer, and we find that the admission of this number proved "harmless to the ultimate disposition." Chamberlin v. Town of Stoughton, 601 F.3d 25, 37 (1st Cir. 2010); see also Kowalski v. Gagne, 914 F.2d 299, 309 (1st Cir. 1990) (rejecting challenge to improperly admitted evidence as "[o]ther ample evidence existed to cast doubt on the credibility of defendant's self-defense theory and to support the jury's finding of culpability").

Next, Defendant claims that Dr. Parisian gave impermissible testimony as to the actions that Wyeth should have taken regarding the development of Prempro. This court made a pretrial ruling prohibiting Dr. Parisian from testifying about any so-called standards of care in the pharmaceutical industry. (Docket No. 154.) During trial, Plaintiffs and Dr. Parisian certainly skirted the line on such impermissible testimony—eliciting objections from Defendants and scolding from this court—but she did not testify as to an actual standard of care in the industry,[7] and her testimony was thoroughly tested by Defendant's counsel during cross-examination.

[7] Moreover, Dr. Parisian's failure to identify such a standard proved immaterial, because the Plaintiff's strict-liability, failure-to-warn claim only required proof that the Defendant "knew, or should have known of the risk inherent in the product." Cruz-Vargas, 348 F.3d at 276 (internal citations and quotation marks removed).

Finally, we reject as unfounded Defendant's argument that this court admitted evidence that lacked a nexus to Plaintiffs' claims. (Docket No. 221 at 22–23.) The Prempak memorandum and the documents regarding the Eastern Cooperative Oncology Group's request for Defendant's support for a study of women who had already been diagnosed with breast cancer were pieces of relevant evidence and the pertinent testimony was subject to adequate cross-examination.

In sum, it is consistent with the evidence adduced at trial that the jury could have so weighed the credibility and strength of the conflicting narratives and reasonably found Defendant liable, in spite of weaknesses in the Plaintiffs' case.

III.

Conclusion

Unfortunately, my view of the evidence is not controlling. I always indicated during the pretrial stage that I understood there were several issues that I would have decided differently if I were the finder of fact. But my view is not controlling here. The jury's decision must be respected, and the motions under Rule 50 and Rule 59 are hereby denied.

One more thing must be said about the Daubert issue raised by Defendant. Any reader of this record should conclude that this court imposed some limitations upon expert testimony, and heard voir dire and cross-examination that called the weight and credibility of Plaintiffs' expert witness testimony into question. But one cannot say that the expert testimony failed the Daubert standard on the evidence before this court. The weight to be given to such testimony was up to the jury to decide, and they did, in what I suspect to be a Solomonic decision that balanced the liability issues with Rivera's concurrent imprudence. The case was fairly tried, and the jury verdict, although perhaps contrary to my own views on the evidence, must be respected.

Defendant's motions for a new trial and for judgment as a matter of law are hereby **DENIED.**

IT IS SO ORDERED.

San Juan, Puerto Rico, this 4th day of February, 2011.

s/José Antonio Fusté
JOSE ANTONIO FUSTE
Chief U.S. District Judge