UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 16-60471-CIV-GAYLES

DENNIS GODELIA and
STERLING YOUMAS,

Plaintiffs,

v.

ZOLL SERVICES, LLC,

Defendant.
_____/

ORDER

THIS CAUSE comes before the Court upon Defendant Zoll Services, LLC's Omnibus Motion *in Limine* [ECF No. 91]. The Court has reviewed the Motion and the record and is otherwise fully advised. For the reasons set forth below, the Motion is granted in part.

Defendant Zoll Services, Inc. ("Defendant") designs, manufactures, and markets the LifeVest, a wearable defibrillator for patients at risk for sudden cardiac arrest. The LifeVest is made to detect life-threatening heart rhythms and deliver a shock to restore normal rhythm. The LifeVest is a Class III medical device, initially approved for sale in 2001 by the Food and Drug Administration ("FDA").

In November 2013, after recovering from a cardiac operation, Debra Godelia began using the LifeVest. On November 18, 2013, Mrs. Godelia experienced a defibrillation event[1] and lost consciousness. Although the parties dispute why, Mrs. Godelia's LifeVest did not administer a shock. Mrs. Godelia remained unconscious until she died in the hospital on November 20, 2013. Plaintiffs Dennis Godelia and Sterling Youmas ("Plaintiffs") then filed this action against

[1] A defibrillation event is either ventricular tachycardia ("VT") (150 beats per minute) or ventricular fibrillation ("VF") (200 beats per minute).

Defendant asserting claims for strict products liability, negligence, fraudulent misrepresentation, fraudulent marketing and promotion, breach of express warranty, negligent misrepresentation, and negligent infliction of emotional distress arising out of Mrs. Godelia's use of the LifeVest.[2]

Defendant now moves to exclude several matters from trial. The Court addresses each in turn.

I. Norman Wong's Analysis and "Audit Report"

Defendant seeks to exclude all evidence relating to a mock inspection and regulatory audit performed by Norman Wong, a retired FDA device expert. Defendant argues that the evidence is a subsequent remedial measure and irrelevant and that its probative value is outweighed by prejudice to Defendant.

Following its 2014 and 2015 routine FDA inspections, Defendant retained Mr. Wong to perform a mock inspection and regulatory audit. In his report (the "Audit Report"), Mr. Wong made findings regarding Defendant's compliance with internal operating procedures and FDA regulations. For each finding, Mr. Wong listed his level of concern (minor or significant) followed by his recommendation. Some of Mr. Wong's findings relate to Defendant's corrective and preventative action for defective solder joints.

The Court does not find that the Audit Report is a subsequent remedial measure. Federal Rule of Evidence 407 provides that:

> When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence; culpable conduct; a defect in a product or its design; or a need for a warning or instruction. But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

[2] After the Court dismissed Plaintiffs' Second Amended Complaint, the Eleventh Circuit reversed in part, finding that, as pled, Plaintiffs' claims were not preempted under the Medical Device Amendments of 1976 ("MDA"). The Eleventh Circuit affirmed this Court's finding that Plaintiffs failed to state a claim for negligent infliction of emotional distress. Following remand and discovery, both sides moved for summary judgment, which the Court denied.

FED. R. EVID. 407. The record does not reflect that Defendant retained Mr. Wong to conduct the audit to make the harm suffered by Mrs. Godelia less likely to occur or to remedy any issues Defendant had with corrective and preventative action for defective solder joints. Rather, as Defendant's 30(b)(6) representative testified, after the FDA issued the results of its inspections and warning letters, Defendant believed that there was a communication issue with the FDA. In response to this belief, Defendant retained Mr. Wong—not to remedy solder defects or regulatory failures but to negate the FDA's findings. Accordingly, this analysis and Audit Report are not subsequent remedial measures and are admissible.[3]

However, as Plaintiffs have noted that they do not intend to rely on any of Mr. Wong's recommendations, the Court will require that the Audit Report be redacted to remove Mr. Wong's recommendations. *See Williams v. Asplundh Tree Expert Co.*, No. 3:05-cv-479-J-33MCR, 2006 WL 2868923, *5 (M.D. Fla. Oct. 6, 2006) ("Reports prepared for a purpose other than remedying a problem may not be excluded by Rule 407 . . . . However, portions of such reports that propose remedies must still be excluded under Rule 407."). The Court also finds that the probative value of Mr. Wong's Audit Report and analysis outweighs any prejudice to Defendant.

Finally, during argument on this issue, Defendant asserted, for the first time, that Mr. Wong's Audit Report is hearsay and therefore inadmissible. However, the Audit Report is admissible within the business records exception to the hearsay rule, provided that Mr. Wong adequately certified that the Audit Reports were made in the regular course of business as required by Federal Rule of Evidence 803(6). *See U.S. v. Frazier*, 53 F.3d 1105, 1110 (10th Cir. 1995)

[3] In addition, even if the audit was conducted in direct response to Mrs. Godelia's LifeVest failing, some courts have held that post-accident investigations or analyses are not subsequent remedial measures. *See Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 430 (5th Cir. 2006) ("the test of the rule 'only prohibits evidence of subsequent remedial measures, not evidence of a party's analysis of its product.'") (quoting *Prentiss & Carlisle Co. v. Koehring-Waterous Div. of Timberjack, Inc.*, 972 F.2d 6, 10 (1st Cir. 1992)).

(Audit report prepared by independent contractor was admissible under business records exception to the hearsay rule). Accordingly, the Motion is denied as to this issue with the caveat that Mr. Wong's certification satisfies the standard set forth in Rule 803(6).

II. Evidence of Incidents Described in the CRFs and MDRs

Defendant seeks to exclude any evidence of incidents described in CRFs and MDRs, arguing they are not similar to this case, their probative value is outweighed by prejudice to Defendant, and they contain inadmissible hearsay.[4]

"Evidence of similar occurrences may be offered to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." *Hessen for Use & Benefit of Allstate Ins. Co. v. Jaguar Cars, Inc.*, 915 F.2d 641, 650 (11th Cir. 1990). To be admissible, (1) "conditions substantially similar to the occurrence in question must have caused the prior accident" and (2) "the prior accident must not have occurred too remote in time." *Jones v. Otis Elevator Co.*, 861 F.2d 655, 661–62 (11th Cir. 1988). "Substantial similarity" "does not require identical circumstances, and allows for some play in the joints depending on the scenario presented and the desired use of the evidence." *Sorrels v. NCL (Bahamas) Ltd.*, 796 F.3d 1275, 1287 (11th Cir. 2015).

During argument, Plaintiffs asserted that the ninety-seven (97) CRFs and MDRs they seek to admit show that Defendants' failed to investigate the root cause of why the cables were breaking. The Court finds this to be substantially similar to their assertion that the purported defect in Mrs. Godelia's LifeVest was due to Defendant's failure to investigate the root cause of broken cables.

[4] CRFs are internal documents generated by Defendant to document communication related to the safety, effectiveness, or performance of a device that has been released for distribution. MDRs, otherwise known as MedWatch reports, are reports Defendant submitted to the FDA to report adverse events or product problems.

Moreover, Defendant created and maintained the CRFs and MDRs. Therefore, they are admissible as opposing party statements and as business record exceptions to the hearsay rule. *See* FED. R. EVID. 801(d)(2) and 803(6). Accordingly, the Motion is denied as to this issue.

III. Evidence Regarding the 2014 Form 483, 2014 Warning Letter, and 2015 Form 483

Defendant moves to exclude any evidence, including expert testimony, regarding the 2014 Form 483, 2014 Warning Letter, and 2015 Form 483 arguing the evidence is irrelevant and that any probative value is exceeded by unfair prejudice to Defendant. The Court disagrees. All three documents relate to the LifeVest Mrs. Godelia was wearing, and they are relevant to whether Defendant complied with federal regulations regarding product complaints and implementation of corrective and preventative action. Moreover, the documents are relevant to when and whether the LifeVest gave appropriate shocks.

In addition, the Court finds that the probative value of the 2014 Form 483, 2014 Warning Letter, and 2015 Form 483 outweighs any prejudice to the Defendant. Accordingly, the Motion is denied as to this issue.

IV. Evidence Regarding Mrs. Godelia's Hypothetical Medical Outcome Had She Not Worn the LifeVest

Defendant moves to exclude any evidence concerning Mrs. Godelia's hypothetical medical outcome had she not worn the LifeVest. There is no dispute that this type of evidence is only admissible through expert medical testimony. The Court reserves ruling on this issue, if raised, during Plaintiff's expert witness testimony.

V. Evidence Regarding After-the-Fact Product Recalls

Defendant moves to exclude any evidence relating to the September 14, 2017, and January 8, 2019, LifeVest product recalls. In response, Plaintiffs state that they do not intend to offer this evidence unless Defendant opens the door. Accordingly, the Motion is granted with respect to this issue.

VI. Testimony from Plaintiffs Concerning Alleged Misrepresentations Made by Zoll to Dr. Jurkovich

Defendant moves to exclude any evidence concerning alleged misrepresentations made by Defendant to Dr. Jurkovich. The Court reserves ruling on this issue, if raised, during trial.

VII. Evidence Regarding Zoll's Overall Profits and Revenues and Acquisition by Asaki-Kasei Corporation

Defendant moves to exclude any evidence regarding Defendant's overall profits and revenues and acquisition by Asaki-Kasei Corporation, arguing punitive damages are not at issue in this case and such evidence would be unfairly prejudicial to Defendant.

In Count 5 of the Second Amended Complaint (Fraudulent Marketing/Promotion), Plaintiffs requested "damages allowed by section 817.41(6), Florida Statutes." [ECF No. 23]. Florida Statue § 817.41(6) states that "[a]ny person prevailing in a civil action for violation of this section shall be awarded costs, including reasonable attorney's fees, and may be awarded punitive damages in addition to actual damages proven." Accordingly, the Court finds that punitive damages are at issue in this action and Plaintiff may present evidence as to punitive damages at trial.

VIII. Evidence of the 2018 Results of the VEST Clinical Trial

Defendant moves to exclude all evidence of the 2018 results of the VEST clinical trial as irrelevant. While the Court agrees that the results of the 2018 clinical trial are not relevant to whether Mrs. Godelia's LifeVest was defective, the Court finds that Dr. Anand may testify about

how he reviewed the clinical trial to bolster his opinion that "[e]arly defibrillation is what permits patients' survival." [ECF No. 93-4 at 6]. Accordingly, the Motion is denied in part on this issue.

IX. Evidence Regarding a Recent Data Breach

Defendant moves to exclude any evidence regarding a data breach that resulted in the exposure of confidential LifeVest patient data. In response, Plaintiffs state that they do not intend to offer this evidence unless Defendant opens the door. Accordingly, the Motion is granted with respect to the data breach.

CONCLUSION

Based on the foregoing, it is

ORDERED AND ADJUDGED that Defendant Zoll Services, LLC's Omnibus Motion *in Limine* [ECF No. 91] is **GRANTED in PART and DENIED in PART** as detailed above.

DONE AND ORDERED in Chambers at Miami, Florida, this 16th day of August, 2019.

DARRIN P. GAYLES
UNITED STATES DISTRICT JUDGE