IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

WOODROW RALPH DRENNEN and LINDA DRENNEN,

Plaintiffs,

v.

CIVIL ACTION NO. 2:22-cv-00357

OLYMPUS AMERICA, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER

The Court has reviewed Defendant Olympus America Inc.'s Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim (Document 5), Defendant Olympus America Inc.'s Memorandum of Law in Support of Its Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim (Document 6), the Plaintiffs' Response to Defendant Olympus America Inc.'s Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim (Document 8), and Defendant Olympus America Inc.'s Reply in Support of Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim (Document 9), as well as the Complaint (Document 1). For the reasons stated herein, the Court finds that the motion should be denied.

FACTUAL ALLEGATIONS¹

The Plaintiffs, Woodrow Ralph Drennen and his wife, Linda Drennen, filed their complaint in this Court² on August 26, 2022. They named Olympus America, Inc., as the Defendant.

¹ The factual allegations set forth herein are drawn from the Plaintiffs' complaint and are treated as true for purpose of the motion to dismiss.

² The matter was initially assigned to Chief Judge Thomas E. Johnston and was reassigned to the undersigned on October 21, 2022.

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Olympus is a medical technology company. It manufactured an ESG-100 device, an electrosurgical generator, that is the subject of this lawsuit. The ESG-100 is a Class 2 device under 21 C.F.R. § 876.4300.

On August 28, 2020, Mr. Drennen underwent a routine screening colonoscopy at Charleston Surgical Hospital in Charleston, West Virginia. The physician discovered two polyps, which he planned to remove using the ESG-100 to power a hot snare. The snare is placed over the polyp, and an electrical current provides heat and pressure to remove the polyp and cauterize the site. As the doctor performed the first polypectomy on Mr. Drennen, the snare overheated and burned more of the colon wall than normal. The wire of the snare "was discolored and had a burned appearance to it when it was removed from Mr. Drennen's colon." (Compl. at \P 12.) The physician "clipped the removal site" that was not properly cauterized and "used a different technique for the second polypectomy." (*Id.* at \P 13.)

The burn from the overheated snare perforated Mr. Drennen's bowel, resulting in a lifethreatening infection. He underwent emergency surgery that night, has received numerous surgeries since, and will need additional surgeries and other medical care. He has been left "permanently scarred, disfigured, and disabled" and his injuries continue "to cause him immense pain and suffering." (*Id.* at ¶16.) Ms. Drennen has and will continue to provide nursing and healthcare services.

The Olympus ESG-100 was properly maintained, and medical personnel ensured that "there was no deviation from Olympus' standard protocol while using the ESG-100 during Mr. Drennen's procedure." (*Id.* at \P 20.) "The medical personnel reported that 'too much energy' 'overheated the snare."" (*Id.* at \P 22.) The ESG-100 manual indicates that a defect or

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malfunction may cause an undesirably high power output. Because the medical personnel suspected a defect, the ESG-100 "was returned to Olympus for examination and to remedy the defective device." (*Id.* at \P 24.) Olympus found a "burn mark on the r28 resistor of the ESG-100 sa communication board" and replaced a faulty component. (*Id.* \P 26.) The defect or malfunction "resulted in high output power, causing Plaintiff to sustain serious injury." (*Id.* at \P 28.) No warning or error notification effectively alerted medical staff of the malfunction, and the ESG-100 "has no independent parallel circuit to limit or govern the heat of the hot snare to the specific limit set by the physician and/or user." (*Id.* at \P 23.)

In mandatory FDA reports, Olympus indicated it had received reports of at least 32 instances of problems with the ESG-100 between March 15, 2016 and April 2, 2021, 25 of which involved injuries or burns to a patient. Thirteen reports described energy output problems. At least two previous instances involved energy output failures and included a finding of burn marks on the communication board in the device. Olympus does not instruct consumers to cease use of devices after a specified life span. The Plaintiffs allege that Olympus failed to perform or rely on adequate testing and research regarding the risks and benefits of the ESG-100.

The Plaintiffs allege that the "Plaintiff and Plaintiff's physicians foreseeably used the ESG-100 for its intended use, and did not misuse, abuse or alter the ESG-100 in an unforeseeable manner," and it was in substantially the same condition during his procedure as when it left the possession of the Defendant. (*Id.* at \P 42–43.) The Plaintiffs further allege that the training and information provided to hospitals and physicians was misleading, insufficient, and incomplete.

The Plaintiffs assert the following causes of action: Count 1: Strict Liability – Manufacturing, Structural, or Design Defect; Count 2: Strict Liability – Defective Product; Count

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3: Strict Liability – Failure to Warn; Count 4- Breach of the Implied Warranty of Merchantability; Count 5 – Negligence; Count 6 – Punitive Damages; and Count 7 – Loss of Consortium. They seek past and future damages to include health care expenses, pain and suffering, lost wages, loss of ability to enjoy life, loss of consortium, emotional distress and mental anguish, annoyance and inconvenience, scarring and disfigurement, the fair value of gratuitously provided physician, nursing, and other healthcare services, punitive damages, pre- and post-judgment interest, and any other appropriate relief.

STANDARD OF REVIEW

A motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted tests the legal sufficiency of a complaint or pleading. *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009); *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Additionally, allegations "must be simple, concise, and direct." Fed. R. Civ. P. 8(d)(1).

"[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atlantic Corp v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, "a complaint must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Moreover, "a complaint [will not] suffice if it tenders naked assertions devoid of further

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factual enhancements." *Iqbal*, 556 U.S. at 678 (*quoting Twombly*, 550 U.S. at 557) (internal quotation marks omitted).

The Court must "accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007). The Court must also "draw[] all reasonable factual inferences from those facts in the plaintiff's favor." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999). However, statements of bare legal conclusions "are not entitled to the assumption of truth" and are insufficient to state a claim. *Iqbal*, 556 U.S. at 679. Furthermore, the court need not "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *E. Shore Mkts., v. J.D. Assocs. Ltd. P'ship,* 213 F.3d 175, 180 (4th Cir. 2000). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice . . . [because courts] 'are not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal,* 556 U.S. at 678 (quoting *Twombly,* 550 U.S. at 555).

To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). In other words, this "plausibility standard requires a plaintiff to demonstrate more than 'a sheer possibility that a defendant has acted unlawfully." *Francis*, 588 F.3d at 193 (quoting *Twombly*, 550 U.S. at 570). A plaintiff must, using the complaint, "articulate facts, when accepted as true, that 'show' that the plaintiff has stated a claim entitling him to relief." *Francis*, 588 F.3d at 193 (quoting *Twombly*, 550 U.S. at 557). "Determining whether a complaint states [on its face] a plausible claim for relief [which can survive a motion to dismiss] will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

DISCUSSION

The Defendant argues that the Complaint does not contain sufficient specific factual allegations to support the causes of action, but instead simply recites the elements and relies on legal conclusions. The Plaintiffs argue that the factual allegations in the complaint are sufficient to state a claim as to each count. In reply, the Defendant argues that the Plaintiffs did not clearly delineate which factual allegations support which cause of action.

As an initial matter, the Defendant urges the Court to consider an Adverse Event Report attached to the motion to dismiss (Document 5-1.) Courts may consider documents attached to a motion to dismiss that are "integral to and explicitly relied on in the complaint" if the authenticity of the document is unchallenged. *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004). The Court does not find the Adverse Event Report to be integral to the complaint. Unlike a contract underlying a contract claim, for example, this case does not turn on the language of the Adverse Event Report. Presuming it is admissible, it will simply be one piece of evidence among others relevant to the cause of Mr. Drennen's injuries and whether the ESG-100 used during his procedure was defective. Considering it before the parties have the opportunity to conduct discovery would improperly treat it as definitive. Therefore, the Court will rely only on the Plaintiffs' allegations in analyzing the sufficiency of the claims.

A. Count 1: Strict Liability – Manufacturing, Structural, or Design Defect

The Defendant argues that the Plaintiffs failed to plead that the ESG-100 was defective at the time it left their control or that it differed from the design or specifications of other typical units. It contends that the allegation that a defect or malfunction caused high power output is insufficient because it "does not identify the specifications that are required to deliver energy nor

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does it plead how the ESG-100 used with the snare during Plaintiffs' procedure differed from other units in the same product line." (Def.'s Mem. at 6.)

In response, the Plaintiffs point to their allegation that the ESG-100 was in the same or substantially similar condition as when it left the Defendant's possession when it malfunctioned. They note that they alleged that Charleston Surgical Hospital maintained the device properly and in accordance with the manufacturer's specifications and that medical staff triple-checked all settings prior to the procedure. They argue that their allegations that "there was a malfunction with the r28 resistor of the ESG-100 sa communications board and in the ESG-100 unit generally that resulted in an excessive discharge of power," and that some, but not all, of Olympus' ESG-100 devices have exhibited similar problems, are sufficient to state a claim. (Pl.s' Resp. at 5.) They contend that the Defendant's position would demand that they prove their case prior to discovery, rather than simply plausibly allege facts supporting their claims. The Plaintiffs recount their allegations that the device used in Mr. Drennen's procedure, like others in adverse incident reports, had an energy output problem resulting in an injury or burn to a patient, and inspection of the device revealed burn marks on the communication board. They note that they included suggestions as to safety features that could have prevented Mr. Drennen's injuries. Thus, they argue that their allegations are sufficient to state a claim.

Under West Virginia law, "a defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (W. Va. 1979). "The cause of action covered by the term 'strict liability in tort' is designed to relieve the plaintiff from proving

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that the manufacturer was negligent in some particular fashion during the manufacturing process and to permit proof of the defective condition of the product as the principal basis of liability." *Id.* at Syl. Pt. 3. "In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use." *Id.* at Syl. Pt. 4 (further providing that the standard of reasonable safeness turns on "what a reasonably prudent manufacturer's standards should have been at the time the product was made").

"To prevail on a manufacturing defect claim, the plaintiff must establish that (1) the product was defective; (2) due to a manufacturing defect; (3) present at the time the product left the manufacturer's control; (4) which proximately caused the plaintiff's injury." *Tyree v. Bos. Sci. Corp.*, No. 2:12-CV-08633, 2014 WL 5359008, at *3 (S.D.W. Va. Oct. 20, 2014) (Goodwin, J.). "To prevail on a design defect claim, the plaintiff must establish that (1) the product was not reasonably safe; (2) for its intended use; (3) due to a defective design feature; (4) which proximately caused the plaintiff's injury." *Id.* at *4.

The Plaintiffs allege that the ESG-100 had a manufacturing or design defect that caused it to put out excessive power without warning, overheating the snare and causing severe injuries. They allege that the ESG-100 was being used for its intended purpose as a medical device used to perform polypectomies during colonoscopies. Because the ESG-100 used in Mr. Drennen's procedure, and some similar devices, experienced this sudden excessive power output which resulted in burns to patients, they were not safe for their intended use. The Plaintiffs allege that the ESG-100 used during his colonoscopy was in substantially the same condition as when it left the Defendant's control and was maintained and used in accordance with the manufacturer's instructions. They allege that the medical personnel ensured the use of the appropriate settings,

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yet the device malfunctioned. After the ESG-100 was returned to the manufacturer, an inspection revealed burn marks on the communication board, and a faulty component was replaced. The Plaintiffs suggest modifications to the design that would prevent excessive power output. If proven, these allegations and reasonable inferences arising from the factual allegations would be sufficient to prove each element of a manufacturing defect or design defect claim.

The Defendants cite cases in which courts required more specific evidence at the summary judgment stage. However, plaintiffs are not required to produce evidence to defend a motion to dismiss. At the pleading stage, plaintiffs must simply allege sufficient facts to plausibly state a claim for relief. The Plaintiffs' complaint places the Defendant on notice of the nature of the manufacturing and design defect claim and the basic facts underlying that claim. Therefore, the motion to dismiss should be denied as to Count 1.

B. Count 2: Strict Liability – Defective Product

The Defendant contends that the Plaintiffs' complaint does not adequately allege the intended use of the ESG-100, how the design rendered it unreasonably unsafe, the design component that rendered it unsafe, standards that should have been followed or how the ESG-100 design was contrary to such standards or identify available alternative designs that would have reduced the risks. The Defendant notes that the Plaintiffs concede that they have not identified the precise nature of the alleged defect. It urges the Court to consider a full Adverse Event Report that found the ESG-100 functioned normally. The Defendant argues that the complaint contains only vague and conclusory allegations to support the defective product claim.

The Plaintiffs indicate that they alleged Count 2 in the alternative to Count 1. They argue that West Virginia precedent permits a plaintiff to prove a product defect under the malfunction

theory based on circumstantial evidence. They contend that they adequately alleged each element: that a malfunction occurred in the product that would not ordinarily happen, that there was no abnormal use of the product, and that there was no reasonable secondary cause for the malfunction. They stress that Olympus' user manual for the device states that undesirably high output power may be emitted in the event of a defect or malfunction in the unit.

"West Virginia law permits plaintiffs to submit multiple products liability theories to the jury." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017) (Goodwin, J.). The West Virginia Supreme Court has established the following standard for plaintiffs to present a strict products liability claim under the malfunction theory:

Circumstantial evidence may be sufficient to make a *prima facie* case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect. Moreover, the plaintiff must show there was neither abnormal use of the product nor a reasonable secondary cause for the malfunction.

Syl. Pt. 4, *Bennett v. Asco Servs., Inc.*, 621 S.E.2d 710, 712–13 (W. Va. 2005) (internal quotation marks and citations omitted).

Many of the same facts and inferences that support Count 1 also support Count 2. The Plaintiffs allege that a malfunction caused the ESG-100 to produce excessive power, overheating the snare. The factual allegations indicate the product is designed to be carefully calibrated to safely generate the amount of power necessary for a given procedure. The Plaintiffs further allege that the Defendant's own manual indicates that excessive power output may result from a malfunction. The Plaintiffs specifically allege that the product was used normally and in accordance with Olympus' specifications, and that there was no reasonable secondary cause for the malfunction. The ESG-100 was the power source for the polypectomy, and the Plaintiffs

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specifically allege that the medical personnel maintained and used the device properly. Therefore, accepting the factual allegations as true, the device must have malfunctioned to overheat the snare, and there is no reasonable secondary cause for the malfunction or the Plaintiffs' injuries. Thus, they have presented factual allegations of each element as to Count 2, and the Defendant's motion to dismiss will be denied.

C. Count 3: Strict Liability – Failure to Warn

The Defendant argues that the Plaintiffs' claims as to Count 3 are similarly conclusory and generic. It contends that the Plaintiffs failed to specify how the warnings, labels, or instructions for the ESG-100 were inadequate, or how any such inadequacy proximately caused Mr. Drennen's injury. The Defendant argues that the Plaintiffs would be required to show that a warning would have altered the physician's treatment. It emphasizes that, under West Virginia law, failure to warn in medical device cases requires a showing that the manufacturer failed to provide reasonable instructions and warnings to health care providers, not direct warnings to patients.

The Plaintiffs argue that the complaint sets forth sufficient allegations to state a failure to warn claim. They contend that warnings that the device or its components required replacement after a specific reasonable lifespan could have prevented Mr. Drennen's injury.

"A defect arising from failure to warn 'covers situations when a product may be safe as designed and manufactured,' but then 'becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner." *Tyree v. Bos. Sci. Corp.*, No. 2:12-CV-08633, 2014 WL 5359008, at *3 (S.D.W. Va. Oct. 20, 2014) (Goodwin, J.) (quoting *llosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 609 (W.Va.1983)). "To substantiate a failure to warn claim under strict liability, the plaintiff must show that the failure to adequately warn 'made

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the product not reasonably safe' and 'that the defect was the probable cause of her injuries.'" *Id.* (quoting *llosky*, 307 S.E.2d at 610).

The Plaintiffs allege that, despite prior instances of similar malfunctions, Olympus provided no warning to medical providers using the device that it should not be used or that components must be replaced after a specified life span. It may reasonably be inferred from the factual allegations, including the allegation that a component was replaced, that the device malfunction resulted because the component had reached the end of its life span and no longer functioned properly. In addition, the Plaintiffs allege that the medical providers were provided insufficient instructions and warnings for use with regard to the ESG-100's propensity to deliver too much energy and any methods to safeguard patients. Thus, the Plaintiffs have alleged sufficient facts to state a plausible claim for relief under the failure to warn theory.

D. Count 4: Breach of the Implied Warranty of Merchantability

The Defendant contends that the claim for breach of the implied warranty of merchantability fails for the same reasons it urged dismissal of the strict product liability claims. It argues that the complaint does not contain sufficient factual allegations detailing what renders the ESG-100 unfit for its ordinary purpose.

The Plaintiffs argue that they alleged that Olympus knew that the ESG-100 would be used for colonoscopies, and that unexpectedly high power output renders it unsafe for that purpose.

West Virginia law provides that goods may breach the implied warranty of merchantability if, among other things, they are not "fit for the ordinary purposes for which such goods are used," are not "adequately contained, packaged, and labeled as the agreement may require," and do not "conform to the promises or affirmations of fact made on the container or label if any." W. Va.

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Code § 46-2-314(2)(c),(e),(f). This Court has previously found that "claims for strict liability and breach of the implied warranty of merchantability are essentially coextensive in products liability actions." *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 545 (S.D.W. Va. 2011) (Copenhaver, J.).

Given the Court's findings with respect to the strict products liability claims, no extensive discussion is needed. In short, the Plaintiffs have plausibly alleged that Olympus sold the ESG-100 to medical providers, including the Charleston Surgical Hospital, for the purpose of performing procedures, including colonoscopies. The device used during Mr. Drennen's procedure put out excessive power despite being maintained and used properly by the medical personnel, causing severe burns and permanent injuries. An electro-surgical generator that puts out excessive power without warning is clearly unsafe and unfit for the purpose of performing polypectomies. *See Raab v. Smith & Nephew, Inc.*, 150 F. Supp. 3d 671, 700 (S.D.W. Va. 2015) (Johnston, J.) ("The allegation that the devices failed, while implanted inside of Mrs. Raab, gives rise to a plausible claim that the Class II components were not fit for the ordinary purpose for which they are used."). Accordingly, the Defendant's motion to dismiss should be denied as to Count 4.

E. Count 5: Negligence

The Defendant argues that Count 5 should be dismissed because the Plaintiffs do not sufficiently allege that it owed Mr. Drennen a duty or breached any such duty. It argues that the complaint asserts only general duties, without identifying the specific duty owed to Mr. Drennen and how it breached that duty. The Plaintiffs argue that a duty to Mr. Drennen, and to patients generally, exists under the three defect claims because the harm is foreseeable.

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The basic elements of a negligence claim are duty, breach of that duty, causation, and damages. "In order to establish a negligence claim in West Virginia, '[a] plaintiff must prove by a preponderance of the evidence that the defendant owed a legal duty to the plaintiff and that by breaching that duty the defendant proximately caused the injuries of the plaintiff." *Cline v. 7-Eleven, Inc.*, 2012 WL 5471761 (N.D.W. Va. Nov. 9, 2012) (citing *Neely v. Belk, Inc.*, 668 S.E.2d 189, 197 (W.Va.2008)). In determining whether a duty exists, "[t]he ultimate test…is found in the foreseeability that harm may result." Syl. pt. 4, *Jones v. Logan Cnty. Bd. of Educ.*, No. 21-0217, 2022 WL 17038200, at *1 (W. Va. Nov. 17, 2022) (explaining that the test is whether "the ordinary man in the defendant's position, knowing what he knew or should have known, [would] anticipate that harm of the general nature of that suffered was likely to result").

The Plaintiffs allege that Olympus was aware of prior similar incidents of excess power output from ESG-100 devices. It is foreseeable that excess power output from a medical device powering a snare used internally on patients would cause the type of harm suffered by Mr. Drennen. Therefore, the Plaintiffs' allegations, if proven, would support a finding that Olympus owed Mr. Drennen a duty of care and breached that duty by failing to ensure the safety of its products, as discussed more fully above. Mr. Drennen has alleged that he was injured by the defective or malfunctioning device, and that he has suffered serious injuries. Thus, the Court finds that he has alleged facts sufficient to state a plausible claim for negligence, and the Defendant's motion to dismiss will be denied as to Count 5.

F. Count 6: Punitive Damages

The Defendant contends that the claim for punitive damages should be dismissed because the Plaintiffs "fail to allege any behavior that meets West Virginia's threshold for punitive liability." (Def.'s Mem. at 17.) The Plaintiffs cite their allegation that Olympus was aware of 32 adverse incident reports, some involving similar problems, yet failed to remedy the issue with the ESG-100.

Punitive damages are recoverable in West Virginia "where gross fraud, malice, oppression, or wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others appear." Syl. Pt. 4, *Alkire v. First Nat. Bank of Parsons*, 475 S.E.2d 122, 124 (W. Va. 1996). The Plaintiffs allege that Olympus was on notice of problems with energy output on the ESG-100 for years prior to Mr. Drennen's colonoscopy yet failed to take any action to remedy the issue. They allege that Olympus failed to provide adequate warnings or perform proper and adequate testing. They also allege that Olympus provided incomplete and misleading training to healthcare providers in order to increase sales. If proven, those facts could permit a jury to find that Olympus's conduct was wanton, willful, or reckless. Therefore, the Defendant's motion to dismiss the claim for punitive damages should be denied.

CONCLUSION

Wherefore, after thorough review and careful consideration, the Court **ORDERS** that *Defendant Olympus America Inc.'s Motion to Dismiss Plaintiffs' Complaint for Failure to State a Claim* (Document 5) be **DENIED**. The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and to any unrepresented party.

ENTER: December 28, 2022

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UNITED STATES DISTRICT JUDGE SOUTHERN DISTRICT OF WEST VIRGINIA