UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

MARIA OLIVIA AGUILAR, Plaintiff, v. AMERICAN MEDICAL SYSTEMS, INC. Defendant.	No. 2:20-CV-00259-SAB **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Before the Court is Defendant's Motion for Summary Judgment, ECF No. 24. A videoconference was held on November 2, 2020. Plaintiff was represented by Jonathan Orent. Defendant was represented by Regina Nelson and Anne Talcott.

Plaintiff initially filed her Complaint in the Southern District of West Virginia as part of the Multi-District Litigation proceedings, *In Re: American Medical Systems, Inc. Pelvic Repair System Products Liability Litigation, MDL 2325*. ECF No. 1. Plaintiff asserts she was implanted with Defendant's Monarc Subfacial Hammock. *Id.* She is alleging sixteen counts, including (Ct. I) Negligence; (Ct. II) Strict Liability – Design Defect; (Ct. III) Strict Liability – Manufacturing Defect; (Ct. IV) Strict Liability – Failure to Warn; (Ct. V) Strict Liability – Defective Product; (Ct. VI) Breach of Express Warranty; (Ct. VII) Breach of Implied Warranty; (Ct. VIII) Fraudulent Concealment; (Ct. IX) Constructive Fraud; (Ct. X) Discovery Rule, Tolling and Fraudulent Concealment;

(Ct. XI) Negligent Misrepresentation; (Ct. XII) Negligent Infliction of Emotional Distress; (Ct. XIII) Violation of Consumer Protection Law; (Ct. XIV) Gross Negligence; (Ct. XV) Unjust Enrichment; and (Ct. XVII) Punitive Damages.

Defendant now moves for summary judgment on all of Plaintiff's claims. In her response, Plaintiff indicates she is withdrawing her claims relating to Manufacturing defects, Express and Implied Warranty, Fraudulent Concealment, Constructive Fraud, Negligent Misrepresentation, Negligent Infliction of Emotional Distress, Unjust Enrichment and violations of the Washington Consumer Protection laws. ECF No. 28. Based on this representation, the Court will grant Defendant's Motion for Summary Judgment with respect to Cts. I, III, V-XV. The Court dismisses any claims for punitive damages as these are not available for Washington Products Liability claims. *See Steele v. Johnson*, 76 Wash.2d 750, 753 (1969) (holding punitive damages are not permitted under Washington law unless expressly permitted by statute). Thus, the remaining claims are Ct. II, Design Defect, and Ct. IV, Failure to Warn.

Motion Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). There is no genuine issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The moving party has the initial burden of showing the absence of a genuine issue of fact for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party meets its initial burden, the non-moving party must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248.

In addition to showing there are no questions of material fact, the moving party must also show it is entitled to judgment as a matter of law. *Smith v. Univ. of*

Wash. Law Sch., 233 F.3d 1188, 1193 (9th Cir. 2000). The moving party is entitled to judgment as a matter of law when the non-moving party fails to make a sufficient showing on an essential element of a claim on which the non-moving party has the burden of proof. *Celotex*, 477 U.S. at 323. The non-moving party cannot rely on conclusory allegations alone to create an issue of material fact. *Hansen v. United States*, 7 F.3d 137, 138 (9th Cir. 1993).

When considering a motion for summary judgment, a court may neither weigh the evidence nor assess credibility; instead, "the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255.

Background Facts

On June 30, 2008, Dr. Margaret L. Hutchinson performed an anterior colporrhaphy, posterior repair, Mirena IUD placement, labiaplasty and insertion of the Monarc Subfacial Hammock at Swedish Medical Center in Seattle, Washington. ECF No. 1. Plaintiff asserts the implant caused pain, erosion, urinary problems, recurrence, bleeding, dyspareunia and vaginal scarring. ECF No. 6.

Washington Products Liability Act

1. (Ct. IV) – Strict Liability Failure to Warn claim

Plaintiff's Failure to Warn claim falls under the Washington Product Liability Act (WPLA).[1] *Taylor v. Intuitive Surg., Inc.*, 187 Wash.2d 743, 754 (2017) ("The WPLA governs product-related harm claims based on a manufacturer's failure to warn."). Section 7.72.080 provides, in part:

> (1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed

[1] The parties agree that Washington substantive law applies to Plaintiff's Failure to Warn claim.

> or not reasonably safe because adequate warnings or instructions were not provided.
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> (b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.
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> (c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

Washington law follows the learned intermediary doctrine. *Taylor*, 187 Wash.2d at 757. Under this doctrine, while the manufacturer has a duty to warn patients of product risks, it can satisfy this duty by properly warning the doctor (the learned intermediary), who then takes on the responsibility of communicating those warnings to the patient. *Terhune v. A.H. Robins Co.*, 90 Wash.2d 9, 17 (1978).

a. Adequacy of the Warnings

A manufacturer has a duty to provide warnings or instructions commensurate with its harm and the risk. *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wash. App. 335, 345 (2005). Generally, the adequacy of a warning will be a question of fact. *Id.* at 343. However, a question of fact can be determined as a matter of law when reasonable minds can reach only one conclusion from the admissible evidence. *Id.* To determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. *Id.*

at 344. The trier of fact must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved using the device. *Id.*

A plaintiff is not required to establish the exact wording of the alternative warning. *Ayers by and through Ayers v. Johnson & Johnson Baby Prod. Co.*, 117 Wash.2d 747, 756 (1991). Requiring plaintiffs in failure to warn cases to establish the exact wording of an alternative warning would impose too onerous a burden. *Id.* The jury might agree that a certain type of warning should have been provided, but they might not agree among themselves as to exactly how that warning should have been worded. *Id.* The statute's requirement that "the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate" is satisfied if the plaintiff specifies the substance of the warning. *Id.*

Here, Plaintiff relies on the testimony of her general causation experts, Dr. Galloway, Dr. Parisian and Dr. Blavis, who have opined that the warnings were not adequate. This is enough to defeat summary judgment on the question as to whether the warnings were adequate.

b. Proximate Cause

Under Washington law, "[i]n a products liability suit alleging inadequate warnings, the plaintiff must show that his or her injury was proximately caused by a product that was 'not reasonably safe because adequate warnings or instructions were not provided.'" *Ayers*, 117 Wash.2d at 752. To show proximate causation, the plaintiff must show both cause in fact and legal causation. *Id.* (citation omitted). "Cause in fact refers to the actual connection between the act and an injury—but for the act, the injury would not have occurred." *Sherman v. Pfizer, Inc.*, 8 Wash. App.2d 686, 687 (2019). Legal causation depends on considerations of "logic, common sense, justice, policy, and precedent." *Ayers*, 117 Wash.2d. at 756. (quotation omitted). It involves the "determination of whether liability should

attach as a matter of law given the existence of cause in fact." *Id*. (quotation omitted).

Cause in fact is generally a question for the jury. *Baughn v. Honda Motor Co., Ltd.*, 107 Wash.2d 127, 142 (1986). When the facts are undisputed, however, so that an inference can be made that is incapable of reasonable doubt or difference of opinion, factual causation may be a question of law for the court. *Id*.

Defendant relies on the testimony of Dr. Hutchison, Plaintiff's physician who implanted the device in question, to assert that Plaintiff is unable to establish causation based on an alleged inadequate warning. Dr. Hutchison testified that she was aware of the relevant risks when she implanted the Monarc in Plaintiff; she reviewed the published literature regarding the Monarc, and the risks of the Monarc were well known in the medical community. When asked if "knowing everything you know today about the Monarc, do you stand by your decision that you made in 2008 to use the Monarc to treat [Plaintiff's] stress urinary incontinence?," Dr. Hutchison answered, "Yes."

Defendant argues that Dr. Hutchison's statements preclude Plaintiff from showing that a different, increased warning would have persuaded Dr. Hutchison to take a different course of action.

The Court disagrees with Defendant that Dr. Hutchison's statement permits the Court, rather than the jury, to determine proximate cause. First, it is not clear from the record what Dr. Hutchison knew about the Monarc when she made her statement. Also, it is not clear from the record what risks were well known in the medical community. A reasonable jury would need to hear what Dr. Hutchison now knows about the Monarc before it can access the significance of her statement regarding her decision. Dr. Hutchison's answer to counsel's question is not sufficient to take the proximate cause decision from the jury. Second, the Court does not consider Dr. Hutchison an unbiased witness. Thus, it will be important for

the jury to hear and evaluate her testimony on both direct and cross-examination and determine her credibility.

Because genuine issues of material fact regarding whether the warnings provided by Defendant were adequate and whether the failure to provide adequate warnings proximately caused Plaintiff's injuries, summary judgment on Plaintiff's failure to warn claim is not appropriate.

2. Strict Liability – Design Defect claim

Under the Washington Product Liability Act, to show a product was defectively designed, a plaintiff must show that a manufacturer's product was not reasonably safe as designed and caused harm to the plaintiff. Wash. Rev. Code § 7.72.030.

"There is no debate" that Washington courts have expressly adopted the comment *k* exception to strict liability in the case of unavoidably unsafe products. *Ruiz–Guzman v. Amvac Chem. Corp.*, 141 Wash.2d 493, 506 (2000) (citation omitted). Moreover, the Ninth Circuit noted the Washington Supreme Court has indicated that comment k provides an exemption for medical products generally. *Transue v. Aesthetech Corp.*, 341 F.3d 911, 915 (9th Cir. 2003).[2] After reviewing

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[2] The *Transue* court relied on the following cases: (1) In *Terhune,* the court found that the Dalkon Shield implanted contraceptive device qualified for comment k exemption because of its availability only through a physician. 90 Wash.2d 9 (1978); (2) in *Rogers v. Miles Lab., Inc.*, the court held that blood and blood products qualify for comment k exemption. 116 Wash.2d 195 (1991) (en banc); (3) a plurality of the court in *Young v. Key Pharmaceuticals, Inc.*, held that "a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug." 130 Wash.2d 160 (1996) (en banc); and (4) in *Ruiz–Guzman*, the court held that "[b]y its own terms, comment k is especially applicable to medical products. The exceptions for

Washington caselaw, the Circuit concluded that "if the Washington Supreme Court were to encounter this precise issue, the most reasonable inference from existing precedents is that it would likely follow its dicta in *Ruiz-Guzman* and hold that all medical devices and products will be afforded comment *k* exemption." *Id.*

The Court is bound to follow the holding in *Transue*. That said, while comment *k* has application with respect to medical devices, it only applies when a product is "accompanied by adequate warnings." *Taylor*, 187 Wash.2d at 764 (quoting *Young v. Key Pharm., Inc.*, 130 Wash.2d 160, 184 (1996) (Madsen, J., dissenting) ("Exemption from strict liability under comment *k* is expressly limited to products accompanied by *adequate warnings*. Stated another way—adequate warnings are a predicate to application of comment *k* by the express terms of the comment."). Because genuine issues of material fact exist with respect to whether the warnings were adequate, the Court cannot say, as a matter of law, that summary judgment on Plaintiff's strict liability design defect claim should be granted.[3]

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medical products recognize the unique protection provided to the consumers of such products by the prescribing physician (and/ or pharmacist) intermediary." 141 Wash.2d at 508.

[3] Moreover, even if comment *k* applies, this does not necessarily mean Plaintiff's design defect claim must be dismissed. Rather, Washington law permits design defect claims based on a negligence standard. *See* WPJI 111.02.01.

Accordingly, **IT IS HEREBY ORDERED**:

1. Defendant's Motion for Summary Judgment, ECF No. 24, is **GRANTED**, in part; and **DENIED**, in part.

2. The following claims are dismissed: (Ct. I) Negligence; (Ct. III) Strict Liability – Manufacturing Defect; (Ct. V) Strict Liability – Defective Product; (Ct. VI) Breach of Express Warranty; (Ct. VII) Breach of Implied Warranty; (Ct. VIII) Fraudulent Concealment; (Ct. IX) Constructive Fraud; (Ct. X) Discovery Rule, Tolling and Fraudulent Concealment; (Ct. XI) Negligent Misrepresentation; (Ct. XII) Negligent Infliction of Emotional Distress; (Ct. XIII) Violation of Consumer Protection Law; (Ct. XIV) Gross Negligence; (Ct. XV) Unjust Enrichment; and (Ct. XVII) Punitive Damages.

IT IS SO ORDERED. The Clerk of Court is directed to enter this Order and forward copies to counsel.

DATED this 5th day of November 2020.

Stanley A. Bastian
U.S. District Judgre