IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

JURGEN VOLLRATH, Plaintiff, v. **DePUY SYNTHES BUSINESS ENTITIES, JOHNSON & JOHNSON, DOES I through X, and ROE Business Entities I through X**, Defendants.	Case No. 3:19-cv-1577-SI **OPINION AND ORDER**

Jurgen Vollrath, Plaintiff, *pro se*.

Anne M. Talcott, SCHWABE, WILLIAMSON & WYATT PC, 1211 SW Fifth Avenue, Suite 1900, Portland, OR 97204; David L. Ferrera, NUTTER MCCLENNEN & FISH LLP, 155 Seaport Boulevard, Boston, MA 02210; David R. Schmahmann, LAW OFFICE OF DAVID SCHMAHMANN, 1577 Beacon Street, Brookline, MA 02446. Of Attorneys for Defendants DePuy Synthes Business Entities and Johnson & Johnson.

Michael H. Simon, District Judge.

Plaintiff Jurgen Vollrath (Vollrath), *pro se*, brings this lawsuit against Defendants DePuy Synthes Business Entities (DePuy) (whom Defendants explain is properly known as "Medical Device Business Services, Inc.") and Johnson & Johnson (collectively, Defendants). In his Complaint, Vollrath alleges that DePuy, a wholly owned subsidiary of Johnson & Johnson, manufactured and sold S-ROM modular hip implants with a separate titanium stem, sleeve, and

head. Vollrath contends that this modular hip is defective. Vollrath alleges that, in December 2010, he had hip replacement surgery, during which this defective S-ROM modular hip, manufactured by DePuy, was implanted in Plaintiff and that that modular hip failed in September 2017. Vollrath asserts claims of negligence, failure to warn, breach of warranty, willful concealment and fraud, and intentional infliction of emotional distress, and he seeks unspecified economic damages for medical expenses and non-economic damages in the amount of $9 million for past, present, and future pain and suffering. ECF 1-1, at 16-19. Before the Court is Defendants' Motion for Summary Judgment (ECF 45), in which Defendants move to exclude the proposed testimony of Vollrath's two expert witnesses and for summary judgment in favor of Defendants. For the following reasons, the Court denies Defendants' motion to exclude the testimony of Plaintiff's expert witnesses but grant Defendants' motion for summary judgment.

STANDARDS

A. Daubert Motion to Strike Expert Reports

Rule 702 of the Federal Rules of Evidence (FRE) governs the admissibility of expert testimony. It provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

"Under *Daubert*[1] and its progeny, including *Daubert II*,[2] a district court's inquiry into admissibility is a flexible one." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1043 (9th Cir. 2014) (citing *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013)). In evaluating proffered expert testimony, the trial court is "a gatekeeper, not a fact finder." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quotation marks omitted). "[T]he trial court must assure that the expert testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 564 (quotation marks omitted). "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Id.* at 565 (quotation marks omitted). "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Id.* at 564. The judge must "screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable." *City of Pomona*, 750 F.3d at 1043 (quoting *Alaska Rent-A-Car*, 738 F.3d at 969). In short, "[t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." *Id.* at 969-70 (alteration in original) (quoting *Alaska Rent-A-Car*, 738 F.3d at 969-70).

Further, the court must assess an expert's reasoning or methodology, using, when appropriate, criteria such as testability, publication in peer-reviewed literature, known or potential error rate, and general acceptance. *See Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463-64 (9th Cir. 2014) (en banc). But these factors are "meant to be helpful, not

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[1] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[2] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995).

definitive, and the trial court has discretion to decide how to test an expert's reliability as well as whether the testimony is reliable, based on the particular circumstances of the particular case." *Primiano*, 598 F.3d at 564 (citations and quotation marks omitted).

The test "is not the correctness of the expert's conclusions but the soundness of his methodology." *Primiano*, 598 F.3d at 564 (quotation marks omitted). "The objective of [*Daubert's* gatekeeping requirement] is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 149. When an expert meets the threshold established by FRE 702, the expert may testify and the fact finder decides how much weight to give that testimony. *Primiano*, 598 F.3d at 565. Challenges that go to the weight of the evidence are within the province of a fact finder, not a trial court judge. *City of Pomona*, 750 F.3d at 1044. "A district court should not make credibility determinations that are reserved for the jury." *Id*.

B. Motion for Summary Judgment

A party is entitled to summary judgment 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). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Clicks Billiards Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1257 (9th Cir. 2001). Although "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for summary judgment," the "mere existence of a scintilla of evidence in support of

the plaintiff's position [is] insufficient . . . ." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 255 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation and quotation marks omitted).

BACKGROUND

Vollrath was born in 1962. ECF 46-5, at 53:16-22. He had his first hip replacement in 2003. *Id.* at 138:5-10. In 2010, Vollrath presented to Dr. William Griffin at OrthoCarolina Hip and Knee in Charlotte, North Carolina, complaining of pain in both hips that severely limited his physical activity. *Id.* at 155:19-156:17. After some discussions regarding the risks of the surgery, Vollrath elected to move forward with left total hip replacement surgery with Dr. Griffin. *Id.* at 156:18-161:21. On December 2, 2010, Vollrath underwent the surgery, during which Dr. Griffith implanted the S-ROM modular hip system. *Id.* at 161:12-21; *id.* at 169:19-24.

Following the surgery, Vollrath remained physically active, engaging in interval training as well as using an elliptical machine and, on one occasion, cycling from Seattle to Portland over a five-day period. *Id.* at 27:21-30:14. He exercised, on average, five days a week. *Id.* at 29:13-14. Vollrath no longer ran as a form of exercise following his surgery. *Id.* at 30:1-5.

In September 2017, Vollrath experienced a stab of pain and the inability to put weight on his left leg. *Id.* at 175:7-23. He presented to the Emergency Room at Legacy Meridian Park, where X-rays revealed a fracture of his S-ROM femoral stem. *Id.* at 177:9-14. Dr. Jacob Adams attended to Vollrath, and, following a "long, lengthy discussion" regarding Vollrath's condition and revision surgery, Dr. Adams conducted the revision surgery. *Id.* at 179:13-182:9. Vollrath now brings suit against Defendants, the manufacturer and seller of the S-ROM modular hip, asserting claims of negligence, failure to warn, breach of warranty, willful concealment and fraud, and intentional infliction of emotional distress, stemming from the failure of the S-ROM

modular hip. At oral argument on Defendants' motion for summary judgment, Vollrath voluntarily dismissed his willful concealment and fraud claim and his intentional infliction of emotional distress claim.

DISCUSSION

In their motion for summary judgment, Defendants first argue that Vollrath's only two expert witnesses do not meet the admissibility requirements of FRE 702 of the Federal Rules of Evidence, and so the Court should exclude their testimony. In Defendants' view, if the Court excludes Vollrath's proposed expert testimony, the Court must enter summary judgment for Defendants, because Vollrath's claims cannot proceed without admissible expert testimony to support his allegation that the S-ROM modular hip was defective. Defendants next argue that Vollrath's warning defect claim fails because the surgeon who implanted the modular hip was fully apprised of the risks of using such a device. Defendants' final argument is that, to the extent any of Vollrath's claims are based on Defendants' alleged failure to comply with applicable U.S. Food and Drug Administration (FDA) regulations regarding the S-ROM, those claims are preempted. The Court first considers the admissibility of the experts' proposed testimony.

A. Expert Testimony Admissibility

Defendants purport to challenge the admissibility of Vollrath's proposed experts' testimony based on each of the four requirements of FRE 702—their scientific knowledge, whether their testimony is based on sufficient facts or data, whether their testimony is the product of reliable principles and methods, and whether they applied the principles and methods to the facts of this case. Each of Defendants' arguments regarding the inadmissibility of Vollrath's experts' testimony, however, rests on one basic contention: that because the experts are not medical professionals, they are not qualified to opine on any potential defects in Vollrath's hip replacement.

Vollrath offers the testimony of two expert witnesses: Professor Christopher Higgins and Dr. Dan Danks. Professor Higgins is a structural engineer. ECF 48-13, at 31:2. Vollrath hired Professor Higgins "[t]o calculate the stresses that would be produced on the stem of the prosthesis under different offset dimensions." *Id.*, at 59:4-12. Professor Higgins concluded that "[w]ith a larger offset, larger stresses can have a detrimental impact on fatigue life." *Id.* at 120:25-121:2. Professor Higgins specifically stated during his deposition that he would not offer an opinion on whether there was anything defective about the design or materials in this particular device. *Id.* at 60:6-10.

Dr. Danks is a metallurgist and tribologist,[3] with expertise in, among other things, casting foundations, railroads, and oil and gas. ECF 48-14, at 58:23-59:14. Dr. Danks testified that he examined the implant in question to determine the nature of the fracture. *Id.* at 37:22-38:2. Specifically, Dr. Danks testified that there are two major categories of fractures: a sudden fracture as a result of a single event, and a fatigue failure that occurs over a longer period of time, and that the failure in this case was a fatigue failure. *Id.* at 38:8-39:9. Dr. Danks' testimony was cabined similarly to that of Professor Higgins:

> Q. I guess, Dr. Danks, in fairness to you and to your long history in metallurgy, I just want to make sure that you're not painting outside the lines, to be blunt. I want to make sure that your opinion is confined to your expertise here.
>
> Your expertise basically is, I examined the surface. I said this was a fatigue failure. I gave some other details about the nature of the fatigue failure.
>
> And that is the sum and substance of your opinions in this case; am I right?
>
> A. Yes, I think that is a fair characterization.

[3] "Tribology is the study of wear and friction." ECF 48-14, 17:7-8.

Id. at 42:16-43:3. Later in his deposition, Dr. Danks further clarified the limited scope of his testimony:

> Q. So you can't give any information as to whether or not this is an excellent device in terms of its performance, an average device, or a below-average device?
>
> A. That is correct. I cannot.
>
> Q. And you're not offering any opinions in this case about this device and its design and material at all; correct?
>
> A. Just on the failure analysis of the -- of the part itself.

Id. at 57:12-21. Neither Professor Higgins nor Dr. Danks have a medical background, and neither have education, training, or experience in orthopedics, biomaterials, anatomy, or physiology.

Defendants, however, advance no argument that these two experts are unqualified in their respective fields, that their reports lack the rigor or methodology that those fields require, or that their proposed testimony is irrelevant or unhelpful. In fact, Defendants clarified at oral argument that they do not disagree that the two experts are qualified to give expert testimony in their respective areas of expertise and do not challenge their conclusions regarding the impact of larger offsets on fatigue and that the failure here was the result of fatigue. ECF 45, at 14; *id.* at 16. Defendants' sole argument in support of excluding this proposed testimony is that because the experts are not *medical* experts—or medical device experts—that their testimony does not present a genuine issue of material fact.

The Court finds the Ninth Circuit's analysis in *Stilwell v. Smith & Nephew, Inc.* instructive. 482 F.3d 1187 (9th Cir. 2007). In *Stilwell*, the plaintiff had two metal reconstruction nails implanted to stabilize a fracture of her right femur. *Id.* at 1188. The two nails failed, causing the plaintiff pain, suffering, and disability. The plaintiff sued the manufacturer of the devices, asserting claims based strict liability, negligence, and breach of warranty. *Id.* The

defendant moved to bar testimony by plaintiff's expert, a metallurgist, under FRE 702 and *Daubert* and its progeny, arguing that the expert's "expertise as a metallurgist . . . should not qualify him to testify regarding whether a medical device made of metal failed due to a design or manufacturing defect." *Id.* at 1191. The trial court agreed with the defendant, and also granted summary judgment for defendant. *Id.*

The Ninth Circuit on review held that the trial court wrongly excluded the testimony but, upon reviewing the record, affirmed the grant of summary judgment for defendant because the record did not demonstrate that any alleged defects were the cause of the plaintiff's injuries. *Id.* at 1189. The Ninth Circuit described the "twin concerns" of reliability and helpfulness embodied by FRE 702. *Id.* at 1192. The Ninth Circuit explained that a court may exclude testimony that is not reliable, meaning that the methodology is unsound, or that is not helpful, meaning that it does not relate to any issue in the case. *Id.* Applying those standards, the Ninth Circuit held that the trial court erred in "focus[ing] on the helpfulness, rather than the reliability, of [the metallurgist's] testimony" and, by doing so, "mingled the analysis required by [FRE] 702 for the admissibility of expert testimony and [FRCP] 56 for summary judgment." *Id.* at 1192. The trial court, the Ninth Circuit concluded, placed too much emphasis on the eventual merit of the plaintiff's claims, and "seemingly require[ed the metallurgist's] testimony to establish not only the presence of an actual defect but also the causation." *Id.* The trial court had found that because the metallurgist's testimony fell short of guaranteeing that the plaintiff would prevail, that it was not relevant. *Id.* at 1193. The Ninth Circuit held that the trial court "failed to demonstrate that a metallurgist's testimony that the metal device was both poorly manufactured and could have been designed to last longer than it did is not relevant to this products liability case." *Id.*

Like the defendants in *Stilwell*, Defendants here do not argue that the opinions of Professor Higgins and Dr. Danks are unreliable or unhelpful, but rather argue that Professor Higgins and Dr. Danks' testimony is deficient because they are unable to opine on the ultimate issue—whether the S-ROM was defectively designed. As the Ninth Circuit explained, expert testimony need not guarantee that a plaintiff prevail in order to be admissible. *Stilwell*, 482 F.3d at 1193. Because Defendants challenge the admissibility of Vollrath's experts' proposed testimony only on the grounds that it does not guarantee that Vollrath will prevail in his claims, the Court rejects that challenge.

B. Summary Judgment

Having concluded that Vollrath's proposed expert testimony is admissible, the Court considers whether there is a genuine issue of material fact sufficient to survive summary judgment. Following the voluntary dismissal of two of his claims at oral argument, Vollrath's remaining claims—negligence, failure to warn, and breach of warranty—sound in products liability.[4] At oral argument, Vollrath clarified that, in addition to negligence, he alleges strict products liability and, further, that with respect to his strict liability claims, he alleges design defect, manufacturing defect, and failure to warn. The Court first considers Vollrath's negligence claim, then his three theories of strict products liability, and finally his breach of warranty claim.

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[4] Oregon law uses "products liability" as an

> umbrella term for the liability of a manufacturer, seller or other supplier of chattels, to one with whom he is not in privity of contract, who suffers physical harm caused by the chattel. The liability may rest upon the supplier's negligence or upon a warranty, or it may be based on strict liability in tort.

Griffith v. Blatt, 334 Or. 456, 461 n.3 (2002) (citing John W. Wade et al., *Prosser, Wade and Schwartz's Cases and Materials on Torts*, 694 (9th ed. 1994)).

1. Negligence

In his response to a prior motion, Vollrath raised a variety of factual assertions suggesting that the regulatory submission of the S-ROM to the FDA was insufficient, that Defendants' design and manufacturing records are insufficient by FDA standards, and that Defendants' reporting to the FDA was insufficient. ECF 41 (Vollrath's Response to Defendants' Motion to Stay Expert Discovery). Defendants respond to these arguments in their Motion for Summary Judgment, anticipating that Vollrath would again raise them in his response to that motion. ECF 45, at 25. Defendants were correct, as Vollrath's response outlines DePuy's alleged failure to comply with applicable FDA regulations. ECF 47, at 10-11. Vollrath clarified at oral argument that his theory of negligence is that Defendants acted negligently insofar as they did not seek FDA approval when they made certain modifications to the S-ROM.

Defendants argue this claim must fail because there is no private right of action for noncompliance with the FDA regulations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (noting that the Food, Drug, and Cosmetic Act (FDCA) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"). Vollrath, however, does not bring a "fraud-on-the-FDA" claim, like the one at issue in *Buckman*. Rather, he argues that Defendants' failure to secure FDA approval for certain modifications to the S-ROM gives rise to a state law negligence claim, showing that Defendants breached the standard of care.

Under Oregon law, negligence *per se*,

> is a shorthand descriptor for a negligence claim in which the standard of care is expressed by a statute or rule. When a negligence claim otherwise exists, and a statute or rule defines the standard of care expected of a reasonably prudent person under the circumstances, a violation of that statute or rule establishes a presumption of negligence. Once a violation is proven, the burden shifts to the violator to prove that he or she acted reasonably under

> the circumstances. A statute that sets a standard of care addresses only one element of a negligence claim; other elements remain unaffected and must be established.

Deckard v. Bunch, 358 Or. 754, 761 n.6, 370 P.3d 478, 483 (2016) (simplified).

The Oregon Court of Appeals has held that a plaintiff may allege a negligence claim based on failure to comply with FDA regulations. *Axen v. Am. Home Prod. Corp. ex rel. Wyeth-Ayerst Labs.*, 158 Or. App. 292, 307, *opinion adhered to as modified on reconsideration sub nom. Axen v. Am. Home Prod. Corp.*, 160 Or. App. 19 (1999). The court in *Axen* explained

> "When a plaintiff (or a defendant seeking to prove negligence on plaintiff's part) invokes a governmental rule in support of that theory, *the question is whether the rule, though it was not itself meant to create a civil claim, nevertheless so fixes the legal standard of conduct that there is no question of due care left for a factfinder to determine*; in other words, that noncompliance with the rule is negligence as a matter of law. This court long has held that violations of statutory safety rules by themselves provide the element of negligence with respect to those risks that the rules are meant to prevent, at least unless the violator shows that his conduct in fact did not violate the rule under the circumstances." In other words, evidence that AHP had violated the regulations would be evidence that AHP had breached a standard of care established by those regulations. If that breach could be shown to have caused Douglas Axen's injuries, then AHP could be liable under a common-law theory of negligence. Thus, AHP's arguments that the regulations do not provide a cause of action are irrelevant, as are its arguments that plaintiffs did not preserve a statutory negligence claim.

Id. (emphasis added in *Axen*) (quoting *Shahtout v. Emco Garbage Co.*, 298 Or. 598, 601, 695 P.2d 897 (1985)) (citations omitted).

Although the Oregon courts have yet to opine on the effect of *Buckman* on the reasoning in *Axen*, federal courts applying Oregon law have found that *Buckman* does not necessarily foreclose a state law negligence claim. *See Santoro v. Endologix, Inc.*, 2020 WL 6295077, *13 (D. Or. Oct. 6, 2020) (citing *Axen* for the proposition that "Oregon law recognizes a negligence claim for breach of a standard of care based on a violation of federal regulations," and noting that

the plaintiff brought only state law claims, and no claim of fraud on the FDA); *see also Phelps v. Wyeth, Inc.*, 938 F.Supp.2d 1055, 1076 (D. Or. 2013) (citing *Axen* for the proposition that "Oregon courts have held that a plaintiff may allege a negligence per se cause of action against a drug manufacturer for failing to comply with FDA regulations").

Here, the Court need not address whether Vollrath's claims are the type that the Supreme Court considered to be preempted in *Buckman* or could support a negligence *per se* claim under Oregon law. Even if Oregon law permits such a claim, Vollrath has not produced any evidence with respect to Defendants' alleged failure to comply with FDA regulations. Both of Vollrath's expert witnesses stated specifically in their depositions that they reviewed no regulatory material and would offer no opinion on whether the S-ROM implanted in Vollrath had been approved by the FDA. The following exchange occurred during Professor Higgins' deposition:

> Q. Did you review any regulatory materials in connection with the fabrication and testing of this device?
>
> A. I did not.
>
> Q. So as you sit here today you have no opinions with respect to whether or not the device did or did not comply with any of the FDA standards and rules that apply to this device?
>
> A. That is correct.

ECF 48-13, at 17:9-17. A similar exchange took place during Dr. Danks' deposition:

> Q. All right. Did you review any regulatory materials, that is, any of the information that exists that describes what is required of hip stems in terms of performance and fatigue life?
>
> A. I did not.
>
> Q. So you have no opinion as to whether this device did or didn't perform consistent with its regulatory standards as set out by the FDA?
>
> A. That's correct.

ECF 48-14, at 55:16-25. In addition to lacking expert testimony regarding the FDA's consideration of the S-ROM, Vollrath did not provide any documents or other evidence to support his claim that Defendants did not obtain FDA approval for the device. Rather, Vollrath provides one document that purports to be an "internal design change document," ECF 48-5, that appears to describe the details of some modifications to the device. Vollrath, however, provides no context, explanation, or supporting expert testimony to aid the Court in its consideration of that document. In light of the absence of any evidence to support his assertion that Defendants failed to obtain proper FDA approval for the version of the S-ROM implanted in Vollrath, the Court finds that Vollrath's negligence claim cannot survive summary judgment.

2. Strict Products Liability

The Oregon legislature codified portions of Section 402A of the *Restatement (Second) of Torts* (1965) in setting the requirements for a product liability action. Or. Rev. Stat. (ORS) §§ 30.900 *et seq*.; *see also Ewen v. McLean Trucking Co.*, 300 Or. 24, 28-30 (1985) (discussing the history of the enactment of Oregon's product liability statute) (citing to Dominick Vetri, *Legislative Codification of Strict Products Liability Law in Oregon*, 59 Or. L. Rev. 363 (1981)). Under Oregon law, a plaintiff may bring a "product liability civil action," which is defined as:

> a civil action brought against a manufacturer, distributor, seller or lessor of a product for damages for personal injury . . . arising out of:
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> (1) Any design, inspection, testing, manufacturing or other defect in a product;
>
> (2) Any failure to warn regarding a product; or
>
> (3) Any failure to properly instruct in the use of a product.

ORS § 30.900. One who sells or leases a product in a defective condition that is "unreasonably dangerous to the user or consumer or to the property of the user or consumer" is strictly liable for

physical harm or damage to property caused by that condition, if the "seller or lessor is engaged in the business or selling or leasing such a product" and if the "product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold or leased." ORS § 30.920.

At oral argument, Vollrath asserted that he intended to rely on three theories of strict products liability—design defect, manufacturing defect, and failure to warn. The Court considers each of those three theories in turn. Defendants argue that none of Vollrath's products liability claims can survive summary judgment because, even viewing the evidence in a light most favorable to Vollrath, the evidence does not create a genuine issue of material fact. For the reasons explained below, the Court agrees with Defendants.

a. Design Defect

The required elements of a design defect case under Oregon law are as follows:

> (1) the sale or leasing of a product by one engaged in the business of selling or leasing such products; (2) a product that was expected to, and did, reach the user or consumer without substantial change in condition; (3) a product that, when sold, was in a defective condition unreasonably dangerous to the user or consumer; (4) injury to the user or consumer, or damage to his or her property; (5) that was caused by the product's defective condition.

McCathern v. Toyota Motor Corp., 332 Or. 59, 77 n.15 (2001). In this case, it appears that only the third and firth elements are in dispute—whether the S-ROM's allegedly defective condition caused Vollrath's injuries.[5]

[5] Defendants seem to collapse the analysis of whether the S-ROM was defective with whether Vollrath has shown causation. Defendants argue both that there is no defect and that any alleged defect was not the cause of Vollrath's injuries. Specifically, Defendants argue that the cause of the S-ROM's failure and, thus, the cause of Vollrath's injuries was his excessive exercise—*not* any defect in the device. Because, as described below, the Court agrees with Defendants that the evidence is insufficient to create a genuine dispute of material fact as to

Oregon has codified the "consumer expectations" test for determining when a product is defective. *Id.* at 75. This test requires that a plaintiff "prove that, when the product left the defendant's hands, the product was defective and dangerous to an extent beyond that which the ordinary consumer would have expected." *Id.* at 79. "Whether a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer is a factual question to be determined by the jury." *Id.* at 77. A trial court must, however, "ensure that the evidence is sufficient for the jury to make an informed decision about what ordinary consumers expect." *Id.* Because ORS § 30.910 creates a rebuttable presumption that a product is not defective,[6] "a plaintiff may not rely on the bare assertion of a defect from which a jury may infer unreasonable dangerousness; rather, a party must affirmatively put forth some evidence on the issue of dangerousness before the issue may properly be submitted to a jury." *Russell v. Deere & Co.*, 186 Or. App. 78, 83 (2003).

Consumer expectations about how a product should perform under a particular set of circumstances may, in certain cases, be within the realm of jurors' common experience. *McCathern*, 332 Or. at 78. In other cases, however, the products or circumstances involved may be such that the average person would not know what to expect. *Id.* "When a jury is unequipped, either by general background or by facts supplied in the record, to decide whether [a product] failed to perform as safely as an ordinary consumer would have expected . . . additional evidence about the ordinary consumer's expectation is necessary." *Id.* (quotation marks omitted) (first alteration in original). This additional evidence may include advertising or other representations

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whether the S-ROM was defectively designed, the Court does not reach the question of causation.

[6] It is a "disputable presumption" in such cases that "a product as manufactured and sold or leased is not unreasonably dangerous for its intended use." ORS § 30.910.

by the defendant about how a product can be used and will perform.[7] *Id.* at 79. In a design defect case, this additional evidence may consist of risk-utility balancing—proving that a practicable and feasible design alternative was available. *Id.* at 78.

Vollrath bears the burden of demonstrating that the S-ROM modular hip as designed was unreasonably dangerous, based on the consumer expectations test. *Id.* 332 Or. at 75. At oral argument, Vollrath conceded that neither of his experts were able to testify that the S-ROM was defectively designed. Vollrath instead reiterated that Professor Higgins testified that larger offsets can lead to larger stresses that have a detrimental impact on fatigue life, ECF 48-13, at 120:25-121:2, and Dr. Danks testified that the failure in question here was a fatigue failure that occurred over a relatively long period of time, ECF 48-14, at 38:8-39:9. Vollrath contended at oral argument that putting this testimony together paints a picture of why the S-ROM failed in this instance and could lead a trier of fact to the conclusion that it was defectively designed.

Even construing this evidence in the light most favorable to Vollrath, that evidence is not sufficient to meet the requirements of the consumer expectations test under Oregon law. Although the testimony of Dr. Danks and Professor Higgins is admissible and helpful for a trier of fact in considering a design defect claim, Vollrath's claims cannot stand on their limited testimony alone. Not only has Vollrath provided no evidence regarding consumer expectations other than his own subjective expectations about the longevity of the S-ROM, but evidence in the record suggests that, in physically active patients such as Vollrath, the device might fail prematurely. Vollrath has provided the Court only with general scientific information regarding the structure of the device and the nature of this device's failure. ECF 48-13, at 120:25-121:2

[7] Advertising and similar representations about a product is evidence from which the expectation of an ordinary consumer can be adduced, however, "such evidence by itself rarely will demonstrate that a product is defective." *McCathern*, 332 Or. at 79.

(Professor Higgins' testimony regarding larger offsets); ECF 48-14, at 38:8-39:9 (Dr. Danks' testimony regarding fatigue failure). Because the Court finds that this evidence does not create a genuine issue of material fact as to whether the S-ROM's modular hip was defectively designed, summary judgment is appropriate and the Court declines to consider causation.

b. Manufacturing Defect

At oral argument, Vollrath stated that he alleged that the particular S-ROM implanted in him was defectively manufactured. When asked to explain his theory of manufacturing defect, Vollrath explained that the fact that the device failed after less than seven years, rather than the 20-plus years it was expected to last, is evidence that the particular device was defective. Vollrath conceded that he did not offer any additional evidence of a manufacturing defect, beyond the fact of the device's failure.

Under Oregon law, a plaintiff can demonstrate that a product was "mismanufactured"—or, in other words, was defectively manufactured—"relatively simpl[y]," by comparing the product in question "with similar articles made by the same manufacturer." *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 491 (1974). In some cases, however, in which no direct or circumstantial evidence of a manufacturing defect is available, a plaintiff "may nonetheless be able to establish his right to recover, by proving that the product did not perform in keeping with the reasonable expectations of the user." *Heaton v. Ford Motor Co.*, 248 Or. 467, 472 (1967) ("When it is shown that a product failed to meet the reasonable expectations of the user the inference is that there was some sort of defect, a precise definition of which is unnecessary. If the product failed under conditions concerning which an average consumer of that product could have fairly definite expectations, then the jury would have a basis for making an informed judgment upon the existence of a defect.").

Vollrath bases his manufacturing defect claim only on the fact that the S-ROM failed before he expected it would. He did not offer any comparisons of his device to any other, allegedly non-defectively manufactured S-ROMs and, as described above with respect to the design defect claim, offered no evidence as to consumer expectations, beyond his own subjective expectations. In the absence of additional evidence, there is not a genuine issue of material fact for Vollrath's manufacturing defect claim to survive summary judgment.

c. Failure to Warn

Oregon law considers a warning adequate when it is "in such a form that it could reasonably be expected to catch the attention of the reasonably prudent [person] in the circumstances of its use" and its content is "of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person." *Anderson v. Klix Chem. Co.*, 256 Or. 199, 207 (1970), *rev'd on other grounds, Phillips v. Kimwood Mach. Co.*, 269 Or. 485 (1974). More specifically,

> [A user] shall have a fair and adequate notice of the possible consequences of use or even misuse. * * * The rule is that when a manufacturer undertakes by printed instructions to advise of the proper method of using [the] chattel, [the manufacturer] assumes the responsibility of giving accurate and adequate information with respect thereto, including instructions as to the dangers involved in improper use . . . .

Schmeiser v. Trus Joist Corp., 273 Or. 120, 132 (1975) (simplified).

When a warning is given, "the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if [the warning] is followed, is not in defective condition, nor is it unreasonably dangerous." *Benjamin v. Wal-Mart Stores, Inc.*, 185 Or. App. 444, 454 (2002) (quoting *Restatement (Second) of Torts*, comment j) (alteration in original). The adequacy of a warning ordinarily is a question for the jury. *Id.*; *see also Lavoie v. Power Auto, Inc.*, 259 Or. App. 90, 102 (2013). A plaintiff, however, must provide

some evidence from which a jury could find that the warnings were inadequate. *See Safeco Ins. Co. of Am. v. Olstedt Constr., Inc.*, 2004 WL 1050877, at *7-8 (D. Or. May 7, 2004) (granting summary judgment against a failure to warn claim because the evidence showed the warnings provided by the defendants were adequate). A plaintiff alleging failure to warn must show that the manufacturer of a product had reason to anticipate danger from the product's use and that a warning would have made the product safe. *Waddill v. Anchor Hocking*, 149 Or. App. 464, 473-74 (1997), *rev'd on other grounds*, 330 Or. 376 (2000).

At oral argument, Vollrath argued that Defendants failed, in all of their literature on the S-ROM, to warn either patients or physicians of the proneness of the device to fail due to fretting and corrosion and the lack of FDA approval for the extended neck. Based on the above findings that Vollrath has not presented sufficient evidence to create a genuine issue of material fact as to whether the S-ROM was defective and whether Defendants obtained the necessary FDA approval, he likewise cannot meet the additional bar of demonstrating a genuine question of material fact as to whether additional warnings would have rendered the product "safe." Absent particularized evidence that the S-ROM was defective without additional warnings, and that those additional warnings would have cured that defect, Vollrath's failure to warn claim cannot survive summary judgment.

3. Breach of Warranty

Although the Complaint raises a claim for breach of warranty, neither party addressed this claim in their briefing on the Motion for Summary Judgment, and that claim was not discussed at oral argument. Vollrath alleges that "[t]here is an implied warranty that the S-ROM devices designed, manufactured and sold by Defendants are suitable for the purposes for which they are intended," and that Vollrath "used the Modular Hip as intended after it was implanted." Compl. ¶¶ 46-47. Although Vollrath did not cite to a particular statute for this claim, the Court

assumes that it arises from ORS 72.3150, which "provides for an implied warranty of fitness for a particular purpose." *Controltek, Inc. v. Kwikee Enters, Inc.*, 284 Or. 123, 128 (1978). That statute provides:

> Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under ORS 72.3160 an implied warranty that the goods shall be fit for such purpose.

ORS § 72.3150. As discussed above, there is no evidence that the S-ROM implanted in Vollrath was, in fact, defective or unfit for the purpose required, such that any implied warranty might have been breached. Without evidence to that effect, Vollrath's breach of warranty claim does not survive summary judgment.

CONCLUSION

The Court DENIES Defendants' request to exclude the testimony of Plaintiff's two expert witnesses but GRANTS Defendants' Motion for Summary Judgment (ECF 45).

IT IS SO ORDERED.

DATED this 3rd day of February, 2022.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge