UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

RONALD GRUNIG and SHANNON GRUNIG, husband and wife, Plaintiffs, v. JOHNSON & JOHNSON, a New Jersey Corporation, and ETHICON, INC., a New Jersey corporation, Defendants.	Case No. 1:18-cv-00111-BLW **MEMORANDUM DECISION AND ORDER**

INTRODUCTION

Before the Court is Defendants' Johnson & Johnson and Ethicon, Inc. Motion for Summary Judgment. (Dkt. 26.) Also before the Court is Defendants' Motion to Strike. (Dkt. 31.) Oral argument was held on the fully briefed motions on October 22, 2019. After careful consideration of the parties' memoranda, exhibits, and arguments, the Court will grant both the Motion to Strike and the Motion for Summary Judgment.

BACKGROUND

The facts below relate to the claims in this action and are not in dispute, unless otherwise noted.

1. Ethicon Proceed Surgical Mesh

Defendants manufacture and distribute Ethicon Proceed Surgical Mesh, which "is a sterile, thin, flexible, laminate mesh designed for the repair of hernias and other fascial deficiencies."(Dkt. 30-10 at 6; Dkt. 30-3 at 8.) Ethicon Surgical Mesh is at the heart of Plaintiffs' claims in this matter.

The mesh is composed of four layers. (Dkt. 30-3 at 8.) Layer one is oxygenated regenerated cellulose—a plant-based fiber. (ORC). *Id.* at 8-9. Layer two is a 0.8 mm sheet of polymer film. *Id.* Layer three is a flexible plastic "Prolene mesh product." *Id.* at 8. Finally, another layer of polymer film, this time 0.2 mm thick is placed on top of the Prolene mesh. *Id.* at 8-9. During production, the layers are heated and moved through a lamination roll. *Id.* at 8. The process results in the OCR and the Prolene mesh being securely glued to one and other by the adjacent layers of polymer film. *Id.*

The OCR layer is a bioabsorbable product. (Dkt. 30-10 at 6; Dkt. 30-3 at 18.) It is designed to "physically separate" the Prolene mesh "from the underlying tissue and organ surfaces during the wound healing period to minimize tissue

attachment to the mesh." (Dkt. 30-10 at 6.) In line with its function, the ORC layer is designed to be completely absorbed by the body within four (4) weeks of implantation. *Id.* The polymer film also begins to break down and dissipate after surgery. *Id.* The polymer film is designed to be absorbed by the body within six (6) months of implantation. *Id.* Thus, approximately 180 days after a hernia repair surgery, only one layer of the product –the Prolene mesh– remains in the body. In a surgical setting, the Prolene side of the mesh is inserted facing the abdominal wall, thus the OCR side faces the abdominal area and organs. *Id.* It is expected that scar tissue will grow into the Prolene side of the mesh, securing it to abdominal wall allowing for "adequate stabilization" of the fascial defect, i.e. the hernia. *Id.*

2. 2010 Hernia Repair Surgery

In October 2010, Ronald Grunig underwent a ventral hernia repair surgery at Mercy Medical Center in Nampa, Idaho. (Dkt. 1 at 4.) "A hernia is a defect in the connective tissue called facia, and that defect allows the body to push intra-abdominal contents through the defect." (Ballantyne Dep.; Dkt. 30-4 at 10.) The surgery was performed by Dr. Richard C. Ballantyne, D.O. *Id.* According to Dr. Ballantyne, he used Ethicon Proceed Surgical Mesh to repair the hernia, given the hernia's relatively large size. *Id.* at 10-11. There were no complications during the surgery. *Id.* at 11.

Notably, Mr. Grunig had undergone one hernia repair surgery and other abdominal surgeries prior to the October 2010 surgery.[1] (Dkt. 26-2, Ex. A; Dkt. 30-4 at 9.) Dr. Ballantyne noted that the prior abdominal surgeries were significant because "with previous repairs and his surgical repair" Mr. Grunig was "going to have a lot of scar tissue, a lot of adhesions," which would make it more difficult to repair the hernia. (Dkt. 30-4 at 9.) Dr. Ballantyne testified that, he would have discussed these risks with Mr. Grunig, including the risk of creating more adhesions in the performance of another hernia repair. *Id.*

3. 2017 Bowl Obstruction Surgery

In July 2017, Mr. Grunig experienced several days of nausea, vomiting, pain, discomfort, and abdominal distension. (Dkt. 1 at ¶ 14.) Around July 16, 2017, Mr. Grunig was diagnosed with bowel obstruction and was admitted to the hospital. *Id.* On July 24, 2017, Dr. Forrest Fredline, D.O., performed an exploratory laparotomy. (Fredline Dep.; Dkt. 30-6 at 6.) During the procedure, Dr. Fredline observed that there were "dense inflammatory attachments between the loops of small intestine," and stated that these attachments or adhesions "were

[1] Mr. Grunig "had three abdominal surgeries" before 2010, including "a Hartman's procedure for perforated diverticulitis (sigmoid resection), a colostomy reversal, and a prior ventral hernia repair." (Martindale Dep., Dkt. 26-11 at 14.)

between the visera [*sic*], the small intestine, and the anterior abdominal wall mesh, and there was dilated bowel prior to the area of these attachments and decompressed bowel, distal or after the areas of attachments." *Id.*

Dr. Fredline testified that inflammation resultant from abdominal surgery cause bands of tissue –adhesions—to form. *Id.* at 6-7. According to Dr. Fredline, because there was mesh present in Mr. Grunig's abdomen, he had adhesions to the mesh. *Id.* Significantly, Dr. Fredline testified Mr. Grunig "would have had adhesions to the abdominal wall even if he didn't have mesh." *Id.* In sum, Dr. Fredline determined that Mr. Grunig's bowel obstruction was caused by the adhesions. *Id.* During the laparotomy, Dr. Fredline dissected Mr. Grunig's bowel "off of the underlying mesh" and removed "a portion of the mesh" to clear the bowel obstruction. *Id.* The removed portion of the mesh was not retained or analyzed.[2] (Dkt. 30-9.)

[2] Because the portion of removed mesh was not retained, Defendants argue there is no way to determine whether the mesh was the mesh implanted in 2010, or mesh implanted in a previous surgery. (Dkt. 26-2 at 8.) Notably, however, Dr. Ballantyne testified that if there had been mesh implanted during the previous hernia repair, he would have noted that fact in his operative report. (Dkt. 30-4 at 13.) He noted further that he would have also removed any existing mesh prior to installing new mesh because he does not "put mesh on top of mesh." *Id.* It is unclear from the record whether Mr. Grunig had any hernia repairs performed between the 2010 surgery and the 2017 laparotomy.

In March 2018, Mr. Grunig and his wife Shannon Grunig, filed a products liability action against Defendants. (*Compl.*, Dkt. 1.) Therein, Plaintiffs claim Defendants are strictly liable for the defective manufacture and design of the surgical mesh removed from Mr. Grunig, and for failure to warn. Plaintiffs allege also that Defendants are guilty of negligence in design, testing, inspection, manufacture, packaging, labeling, marketing, distributing, and in preparing instructions and warnings regarding the mesh. Plaintiffs seek damages for Mr. Grunig's past, present, and future medical expenses, mental and physical pain and suffering, and for Ms. Grunig's loss of consortium and services. Plaintiffs additionally seek punitive damages.

In June 2018, Defendants filed their answers to the Complaint. (*Answer*, Johnson & Johnson, Dkt. 6; *Answer*, Ethicon, Dkt. 7.) After the discovery period, Defendants filed a joint motion for summary judgment. (Dkt. 26.) Therein, Defendants argue the undisputed material facts show Plaintiffs cannot establish any of their claims as a matter of law, and therefore, this action should be dismissed in its entirety. By separate motion, Defendants also ask the Court to strike portions of an affidavit submitted in support of Plaintiffs' response to the motion for summary judgment. (Dkt. 31.) Defendants argue the affidavit contains inadmissible hearsay statements that do not fall within a recognized hearsay

exception. The Court will set forth the relevant standards of law and analyze the merits of Defendants' motions below.

LEGAL STANDARD

1. Motion for Summary Judgment

Summary judgment is appropriate when the evidence, viewed in the light most favorable to the non-moving party, demonstrates "there is no genuine issue of any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Galen v. County of Los Angeles*, 477 F.3d 652, 658 (9th Cir. 2007).

For summary judgment purposes, an issue must be both "material" and "genuine." An issue is "material" if it affects the outcome of the litigation; an issue is "genuine" if it must be established by "sufficient evidence supporting the claimed factual dispute ... to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Hahn v. Sargent*, 523 F.3d 461, 464 (1st Cir. 1975) (quoting *First Nat. Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968)); *see also British Motor. Car Distrib. v. San Francisco Auto. Indus. Welfare Fund*, 883 F.2d 371, 374 (9th Cir. 1989). "Only admissible evidence may be considered in ruling on a motion for summary judgment." *Stimpson v. Midland Credit Mgmt., Inc.*, 347 F. Supp. 3d 538, 544 (D. Idaho 2018).

"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). Evidence includes "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits…." *DeVries v. DeLaval, Inc.*, 2006 WL 1582179, at *5 (D. Idaho June 1, 2006).

The moving party initially bears the burden to show no material fact is in dispute and a favorable judgment is due as a matter of law. *Celotex*, 477 U.S. at 323. If the moving party meets this initial burden, the non-moving party must identify facts showing a genuine issue for trial to defeat the motion for summary judgment. *Cline v. Indus. Maint. Eng'g & Contracting Co.*, 200 F.3d 1223, 1229 (9th Cir. 2000). The Court must enter summary judgment if the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In considering a motion for summary judgment, a court does not make findings of fact or determine the credibility of witnesses. *See Anderson*, 477 U.S. at 255. Rather, it must draw all inferences and view all evidence in the light most

favorable to the nonmoving party. *See Matsushita*, 475 U.S. at 587-88; *Whitman v. Mineta*, 541 F.3d 929, 931 (9th Cir. 2008).

2. Motion to Strike

Only admissible evidence may be considered in ruling on a motion for summary judgment. *Orr v. Bank of America*, 285 F.3d 764, 773 (9th Cir. 2002); *see also* Fed. R. Civ. P. 56(e). In determining admissibility for summary judgment purposes, it is the contents of the evidence rather than its form that must be considered. *Fraser v. Goodale*, 342 F.3d 1032, 1036-37 (9th Cir. 2003).

If the contents of the evidence could be presented in an admissible form at trial, those contents may be considered on summary judgment even if the evidence itself is hearsay. *Id.* (affirming consideration of hearsay contents of plaintiff's diary at summary judgment because at trial, plaintiff's testimony of contents would not be hearsay). To preserve a hearsay objection, "a party must either move to strike the affidavit or otherwise lodge an objection with the district court." *Pfingston v. Ronan Engineering Co.*, 284 F.3d 999, 1003 (9th Cir. 2002). In the absence of objection, the Court may consider hearsay evidence. *Skillsky v. Lucky Stores, Inc.*, 893 F.2d 1088, 1094 (9th Cir. 1990).

ANALYSIS

1. Motion to Strike Hearsay Statements

The Court turns first to the motion to strike. Defendants assert the Court should strike Paragraph 8 of the Affidavit of Craig Grunig filed as Exhibit K to Ex. 1 to Plaintiffs' response to Defendants' summary judgment motion because it contains inadmissible hearsay statements not subject an exception. (Dkt. 30-12 at 2.) Craig Grunig is the Plaintiffs' son. *Id.* In his affidavit, he attests to having a conversation with Dr. Fredline after the July 24, 2017 surgery. *Id.* The relevant portion of the Craig Grunig's affidavit reads as follows:

> On the same date as the surgery and shortly after it was completed, I was selected by my family to take the post-operative phone call from Dr. Fredline. I spoke with the surgeon, Dr. Forrest Fredline, about the course of and outcome of the surgery. Dr. Fredline described how the hernia mesh from a previous surgery had become entangled with my father's bowel and had grown into it. He told me he had to dissect the hernia mesh away from the small intestine and had to remove a portion of the mesh. Dr. Fredline further stated how the surgical mesh had delaminated. I asked for clarification on that word and he said it was layered and it had come apart. Dr. Fredline expressed some concern that it could happened again, but believed that the surgery had went well overall. Dr. Fredline then asked me to share this information with my father and family. I immediately did so, as my father, mother and sister were next to me in his hospital room.

Id.

Defendants assert Craig Grunig's statements about what Dr. Fredline said during the phone call are inadmissible hearsay. Hearsay is "a statement that the

declarant does not make while testifying at the current […] trial or hearing" and is offered by a party "to prove the truth of the matter asserted in the statement." Fed. R. Evid. 801(c). Hearsay is not admissible unless admission is provided for under the Federal Rules of Evidence, a federal statute, or other rules prescribed by the Supreme Court. Fed. R. Evid. 802. As stated above, only admissible evidence may be considered in ruling on a motion for summary judgment. 347 F. Supp. 3d 538, 544 (D. Idaho 2018).

The statements Craig Grunig attests that Dr. Fredline made in a post-operative phone call are hearsay. They were allegedly made by Dr. Fredline out of court, and are being offered to prove that Dr. Fredline believed the adhesions present in Mr. Grunig were caused by the surgical mesh. Therefore, the Court may not consider the statements in ruling on the present motion for summary judgment unless they are subject to a hearsay exception. Plaintiffs argue, that should the Court determine the Fredline statements are hearsay, two exceptions apply: the present sense impression, articulated in Rule 803(1), and the residual exception, articulated in Rule 807. (Dkt. 37.)

A. The present sense hearsay exception does not apply

A present sense impression is "[a] statement describing or explaining an event or condition, made while or immediately after the declarant perceived it."

Fed. R. Evid. 803(1). The underlying justification for the present sense impression exception "is that substantial contemporaneity of event and statement negate the likelihood of deliberate or conscious misrepresentation. Fed. R. Evid. 803(1) Advisory Committee's Note. "spontaneity is the key factor." *Id.* To qualify under the exception, the "out-of-court statement must be nearly contemporaneous with the incident described and made with little chance for reflection." *Bemis v. Edwards*, 45 F.3d 1369, 1373 (9th Cir. 1995). The proponent of the evidence bears the burden of establishing these requirements by a preponderance of the evidence. *Id.*

The present sense impression exception to hearsay does not apply to the statements allegedly made by Dr. Fredline to Craig Grunig in the post-operative phone call because Plaintiffs have not shown that the phone call was "nearly contemporaneous" with the surgery. Craig Grunig attests that, shortly after the surgery was completed, he was selected by his family to take the post-operative phone call from Dr. Fredline. (Dkt. 30-12 at 2.) Craig Grunig's affidavit does not conclusively establish when the phone call took place in relation to when the surgery was completed. In his deposition, Plaintiff Ronald Grunig related that his son took a phone call from Dr. Fredline sometime after the surgery. (Dkt. 37 at 7-

8.) According to Mr. Grunig, Dr. Fredline called when his son was visiting him in his post-operative room. *Id.* at 7.

Although these facts are evidence that a phone conversation took place, they do not establish that the conversation was "nearly contemporaneous" with completion of the surgery itself. Rather, these facts suggest that Dr. Fredline called the patient's room at a time far enough removed from the surgery for the patient to have been settled into a post-operative position and for members of his family to be admitted into the room to visit him. Furthermore, the nature of the post-surgical call itself suggests that the performing surgeon has had time to gather his or her thoughts sufficient to report out to the patient or the family members on the completed surgery. Dr. Fredline's post-operative statements were not spontaneous statements made with little chance for reflection and, therefore, do not qualify as a present sense impression under Rule 803(1).

B. The residual hearsay exception does not apply

The residual exception to hearsay applies when: "(1) the [out-of-court] statement is supported by sufficient guarantees of trustworthiness—after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement; and (2) it is more probative on the point for

which it is offered than any other evidence that the proponent can obtain through reasonable efforts." Fed. R. Evid. 807(a).

Notably, Rule 807 was amended in 2019 "to fix a number of problems that the courts" encountered in its application. Fed. R. Evid. 2019 Advisory Committee Notes. Under the amended rule, a court must "proceed directly to a determination of whether the hearsay is supported by guarantees of trustworthiness." *Id.* "The amendment specifically requires the court to consider corroborating evidence in the trustworthiness inquiry." *Id.* Finally, the amended "rule provides that the focus for trustworthiness is on circumstantial guarantees surrounding the making of the statement itself, as well as any independent evidence corroborating the statement." *Id.*

The residual exception does not apply to the statements allegedly made by Dr. Fredline during the post-operative phone call because the statements are not supported by sufficient guarantees of trustworthiness. The two most significant statements allegedly made by Dr. Fredline to Craig Grunig are: (1) that the surgical mesh was "entangled" with Mr. Grunig's bowel and had grown into it; and (2) that the layered surgical mesh had delaminated, i.e. the layers had come apart. (Dkt. 30-12 at 2.)

Statements made by Dr. Fredline within his deposition undermine the credibility of the statements he allegedly made during the post-operative phone call. As mentioned above, Dr. Fredline does not recall the phone call with Craig Grunig. (Fredline Depo., Dkt. 26-8 at 53-54.) To this point, Plaintiffs argue that Dr. Fredline's inability to remember details about the surgery adds significant weight to the fact that the phone call took place within a relatively short time period after the surgery. However, as explained above, the record does not establish when the post-operative phone call was made. Even if it did, other evidence negates any trustworthiness gained by the relative temporal proximity between the phone call and the surgery.

For instance, Dr. Fredline testified that he would not use the language "entwined with the mesh" to describe the relationship between the adhesions in Mr. Grunig's bowel. Rather, he would describe the adhesions as those that form "between the bowel and between the mesh" which is located on the abdominal wall. (Fredline Depo., Dkt. 26-8 at 46.) Similarly, Dr. Fredline testified that he is "not familiar" with the nomenclature of a portion of the mesh being "delaminated." *Id.* at 52. Upon the Court's searching of the record, it also appears to be an impossibility that any layer of the mesh other than a single layer would have

remained in Mr. Grunig's body more than 6 years after the date of surgery.[3] (*See* Dkt. 30-13 at 6.) Thus, there is neither direct nor circumstantial evidence to corroborate the statements Dr. Fredline's allegedly made during the post-surgical call. For these reasons, considering the totality of the circumstances, the Court finds the hearsay statements do not have sufficient indicia of trustworthiness to be considered by the Court under the residual exception.

Additionally, as Dr. Fredline is the only individual who could cure the hearsay defects –through his own testimony at trial– it is apparent that such defects would not be cured, given that he did not corroborate Craig Grunig's statements within his previous testimony taken under oath. Therefore, the Court will grant Defendants' motion to strike and will not consider the hearsay statements made in Paragraph 8 of Craig Grunig's affidavit as part of its consideration of the present motion for summary judgment.

2. Motion for Summary Judgment

Defendants assert that the testimony of their experts shows the Proceed Surgical Mesh implanted in Mr. Grunig was not defective and that he did not

[3] As stated herein, approximately half-a-year from the date of implantation, only one layer of the product –the Prolene mesh– remains in the body due to the decomposition of the other bio-absorbable layers. (Dkt. 30-10 at 6.)

develop adhesions as a consequence of defects in the mesh. Defendants argue Plaintiffs have not and can not provide a competent expert report to rebut this testimony, and therefore, the Court should grant summary judgment in Defendants' favor. In the alternative, Defendants argue Plaintiff cannot present competent circumstantial evidence ruling out reasonable alternative explanations for Mr. Grunig's injuries. In response, Plaintiffs assert they may in fact show product defect through circumstantial evidence, and the circumstantial evidence in the record is sufficient to raise a question for the jury.

A. Products Liability Claims – In Tort and Negligence

Generally speaking, there are three main categories of strict liability in product liability cases—manufacturing flaws, design defects, and failure to warn. *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 306 (Idaho 1987); *Mortensen v. Chevron Chemical Co.*, 693 P.2d 1038, 1041 (Idaho 1984). Plaintiffs bring claims under all three categories of strict liability in tort in this case as Counts One, Two, and Three. (Dkt. 1 at 7-14.) Plaintiff brings similar claims under a negligence cause of action in Count Four. *Id.* at 14.

Regardless of whether a products liability-based cause of action is couched in negligence or strict liability, a plaintiff must show that "(1) the product in question was defective, (2) the defect existed at the time the product left the

manufacturer's control, and (3) that the defective product was the proximate cause of the plaintiff's injuries." *Pucket v. Oakfabco, Inc.*, 979 P.2d 1174, 1179 (Idaho 1999) (citing *Corbridge v. Clark Equip. Co.*, 730 P.2d 1005, 1007 (1986)); *Mortensen v. Chevron Chem. Co.*, 693 P.2d 1038, 1041 (Idaho 1984) (citing Restatement § 402A as the basis for finding strict liability for a manufacturing, design defect, or failure to warn); *Farmer v. Internat'l Harvester Co.*, 553 P.2d 1306, 1310 (Idaho 1976) (elements of *prima facia* case are the same regardless of negligence theory or strict liability theory).

Under Idaho law, to prevail on their manufacturing and design defect-based strict liability claims, Plaintiffs must prove that the mesh was defective, i.e. that it malfunctioned, and must also negate other causes for the Mr. Grunig's injuries. *Hansen–Rice, Inc. v. Celotex Corp.*, 414 F.Supp.2d 970, 974 (D. Idaho 2006) (citing *Murray v. Farmers Insurance Co.*, 796 P.2d 101, 106 (Idaho 1990)). The Plaintiffs need not exclude every possible cause but only reasonably likely causes. *Farmer v. Int'l Harvester Co.*, 553 P.2d 1306, 1313 (Idaho 1976).

Generally, "[a] defect may be shown by circumstantial evidence 'without the benefit of expert testimony.'" *Id.* (quoting *Murray*). "However, expert testimony may be required when the facts are beyond the experience of most jurors." *Id.* (citing *Jensen v. Am. Suzuki Motor Corp.*, 35 P.3d 776, 780–81 (Idaho 2001)).

When evidence is extremely technical or difficult to follow, it is the sort that "cries out for expert interpretation." *Id.* at 975.

Defendants assert the nature of facts in this case require Plaintiffs to provide expert testimony to prove the Proceed Surgical Mesh implanted in Mr. Grunig was defective. In response, Plaintiffs assert their claims do not depend on highly technical matters—instead, the facts require only that a juror understand that the mesh is designed to keep the underlying organs from puncturing through the mesh and attaching to the abdominal wall." *Id.* at 12.

Considering facts at issue, as explained below, the Court finds the question of whether the mesh was defective and caused Mr. Grunig's bowl obstruction is the sort of complex issue that requires expert interpretation and proof. The Court strains to imagine a scenario where the circumstantial evidence alone would allow a reasonable juror to conclude that the nature and extent of adhesions in Mr. Grunig's case were made more severe by surgical mesh *because* the mesh contained a defect. As such, the Court will turn to the expert information regarding this question.

Plaintiffs argue that their defect claims are supported by the testimony of Nicholas Popadiuk, Ethicon's Senior Principle Engineer. Plaintiffs argue that his testimony, "to the four (4) layer make-up of the mesh, that it was designed to serve

the remaining life of the patient -more than twenty (20) years if necessary, and how it was designed to prevent underlying organs (small bowl) from piercing through the mesh material." (Dkt. 30 at 14-15.) Upon close review of Mr. Popadiuk's deposition testimony, however, it is clear that Mr. Popadiuk in no way considers himself a medical expert. When questioned about mesh adhering to a bowel, Mr. Popadiuk responded: "That's a clinician type of a question. I am not a clinician." (Dkt. 30-3 at 18.) When pressed further, he stated, "the body is not my cup of tea." *Id.* Notably, Mr. Popadiuk testified that the Proceed Surgical Mesh is "designed to minimize adhesions" but that there is "no product currently on the market that will completely not create – will take adhesions out of any product or any process of the surgical procedure." *Id.*

In support of their motion, Defendants supply two expert reports. First, the report of Marta L. Villaraga, PH.D., a biomedical engineer in the area of medical devices. (Dkt. 26-10 at 2.) Dr. Villaraga opines that, the Proceed Surgical mesh implanted in Mr. Grunig, was not defectively manufactured or designed. *Id.* To form this opinion, Dr. Villaraga reviewed the following related to Proceed Surgical Mesh: (1) the design and manufacturing data (2) the regulatory history (3) the instructions for use and warnings; (3) the manufacturing lot history related to the mesh implanted in Mr. Grunig; and (4) the file in this case. *See id.*

Dr. Villaraga concludes that that the design process was performed in accordance with accepted industry and scientific practices. *Id.* at 62-66. Dr. Villaraga concludes similarly that the Proceed Surgical mesh was not defectively manufactured. *Id.* at 67. Finally, and of import, Dr. Villaraga opines that there are "well known and accepted" risks that surgeries involving implants include infection and inflammation. *Id.* To connect this opinion with the record evidence, Dr. Villaraga pointed to the testimony of Dr. Fredline, wherein he explained that "[i]nflammation in the abdomen presents bands of tissues call [*sic*] adhesions." *Id.*

Defendants' second expert, Robert G. Martindale, M.D. Ph.D., is a surgeon and expert in mesh as a choice for ventral hernia repair. (Dkt. 26-11 at 1-5.) Dr. Martindale opines that, adhesions are a known risk of hernia repair, and can result in the abdominal tissue adhering to the mesh. *Id.* at 8. He additionally opines that, in severe cases, adhesions can result in bowel obstruction. *Id.* Dr. Martindale's conclusions include that: (1) Mr. Grunig had significant adhesions before the mesh was implanted; (2) Mr. Grunig was "particularly susceptible to forming adhesions, as evidence by his medical history;" (3) "the tissue separating barriers used on meshes, including ORC on Proceed mesh, are designed to limit, but can not eliminate, adhesion formation; (4) [n]othing about Mr. Grunig's adhesion

formation is abnormal or suggests a defect with Proceed mesh; and (5) the mesh worked as intended. *Id.* at 16.

The conclusions of Defendants' experts are in line with the operative report and testimony of Dr. Ballantyne, the surgeon who performed Mr. Grunig's 2010 ventral hernia repair surgery. For example, Dr. Ballantyne's operative report and testimony indicate that it took the surgical team approximately an hour to an hour-and-a-half to remove the existing adhesions within Mr. Grunig's abdominal area before performing the surgical repair. (Dkt. 30-4 at 12-13.) According to the operative report, Mr. Grunig "had extensive adhesions" including a portion of "small intestine that was adhesed down lower in the abdomen." (Dkt. 30-5 at 1.)

Dr. Ballantyne testified also that the raw surface area created during the surgery had a high likelihood of re-adhesion "to anything that it" touched, and he was "not surprised" that Mr. Grunig "developed a bowel obstruction, because adhesions in previous surgeries […] are the most common cause for bowel obstruction." *Id.* at 13. Adhesion formation is "the natural body's response for healing." *Id.* at 15.

Dr. Ballantyne testified further that he was aware, in 2010, of the risks associated with using surgical mesh, such as the Ethicon Proceed mesh, in bowel surgeries. *Id.* at 13-14. Consistent with Defendants' experts' opinions, Dr.

Ballantyne testified that the risks of using surgical mesh include inflammation of adhesion formation. *Id.* Notably, the Clinical Evaluation Report for Proceed Surgical Mesh, lists potential adverse reactions of mesh implantation as "those typically associated with surgery of implantable materials, including inflammation" and "adhesion formation." (Dkt. 30-10 at 8.) These potential adverse reactions are included also in the Product Information Kit's Instructions for Use (IFUs). (Dkt. 30-11 at 12.)

Considering the foregoing, the Court finds Plaintiffs have not presented or pointed to expert evidence that would create a genuine issue for the jury as to whether the adhesions that caused Mr. Grunig's bowel obstruction were made more severe or were different from those generally expected in such circumstances. Because of this, no reasonable juror could conclude, absent expert opinion evidence, that a defect caused Mr., Grunig's bowel obstruction. However, even if the Court found the facts in this case are not the sort of technically-based facts that require expert testimony to prove the presence of a defect, Plaintiffs have failed to raise a genuine issue regarding the question of defect based on the circumstantial evidence.

Plaintiffs argue circumstantial evidence shows the surgical mesh implanted in Mr. Grunig in 2010, malfunctioned in less than seven years, despite being

designed to last the lifetime of a patient, and thus was defective. (Dkt. 30 at 10.) To support the assertion, Plaintiffs point the information in Dr. Fredline's operative report, arguing it "demonstrates the mesh was tangled together with the small intestine at the very site of the bowel obstruction." *Id.* at 11. Plaintiffs argue Dr. Fredline's surgical report thus "infers the underlying organ punctured through the mesh material[.]" *Id.* Plaintiffs point also to Dr. Fredline's testimony that there were adhesions between the viscera, the small intestine, and the anterior side of the abdominal wall mesh. *Id.* Plaintiffs point to the fact that Dr. Fredline dissected the bowel off the underlying mesh. Based on the forgoing circumstantial evidence, Plaintiffs argue a reasonable juror could conclude the mesh malfunctioned and reasonably infer the existence of a defective product. *Id.*

Notably, there is no dispute that the mesh implanted in 2010 was not fully intact in 2017 when the bowl obstruction occurred. However, assuming a reasonable juror could infer either a design or manufacturing defect based only on the logic above and without any expert opinion to that effect, Plaintiffs have failed to negate other causes for the Mr. Grunig's injuries. Although Plaintiffs need not exclude every possible cause, they must negate reasonably likely causes. *See Farmer v. Int'l Harvester Co.*, 553 P.2d 1306, 1313 (Idaho 1976).

For instance, there is evidence that Mr. Grunig was particularly susceptible to the formation of adhesions due to his four abdominal surgeries. The testimony of both Dr. Fredline and Dr. Ballantyne, as well as the 2010 operative report, each confirm that Mr. Grunig had extensive adhesions due to prior surgeries. The testimony of both doctors also indicates that any abdominal surgery carries the risk of abdominal adhesions. Notably, Dr. Ballantyne testified that he was aware of and would have made Mr. Grunig aware of the risks of adhesions that are attendant to any abdominal surgery prior to performing the hernia repair surgery in 2010. Further, Dr. Fredline testified that Mr. Grunig likely would have developed adhesions between his small intestine and abdominal wall regardless of whether the mesh was present, i.e. the mesh did not cause the adhesions that resulted in bowl obstruction.

These facts provide the reasonably likely alternative that it was Mr. Grunig's fairly extensive history of abdominal surgeries, including the hernia repair of 2010, that caused the adhesions resulting obstruction of his bowel. Plaintiffs fail to point to any evidence that negates this alternative cause. Instead, the testimony of each surgeon involved in Mr. Grunig's care, as well as Defendants' experts, and Nicholas Popadiuk, Ethicon's Senior Principle Engineer, indicates that the formation of adhesions is an expected and highly common side effect of any

abdominal surgery—including ventral hernia repair surgeries involving the use of surgical mesh.

Provided the foregoing, the Court finds the record taken as a whole could not lead a rational trier of fact to find for Plaintiffs as to the presence of either a design or manufacturing defect. Therefore, there is no genuine issue for trial regarding the presence of a defect in the Proceed Surgical Mesh implanted in Mr. Grunig in 2010. Because proof of defect is an essential element to each of Plaintiffs' defect-based products liability claims the Court will grant the motion to summary judgment as to Claims One, Two, and the relevant portion of Count Four.

B. Failure to Warn – In Tort and Negligence

Failure to warn is also a potential basis for recovery in products liability actions—whether alleged under strict liability or negligence. *Puckett v. Oakfabco, Inc.*, 132 Idaho P.2d 1174, 1181 (1999). A product is defective under the failure to warn theory when "the defendant has reason to anticipate that danger may result from the particular use" of the product "and fails to give adequate warnings of such danger." *Id.* (internal citations omitted). To prevail on a failure to warn claim, a plaintiff "must establish that the failure to warn was the proximate cause" of his injuries. *Hepburn v. Bos. Sci. Corp.*, 2018 WL 2275219, at *6 (D. Idaho May 17, 2018).

Defendants argue the Court should dismiss Plaintiffs' failure to warn claims because they have failed to establish any failure to warn was the proximate cause of Mr. Grunig's injuries, nor have Plaintiffs shown the absence of reasonable secondary causes, as discussed above (citing *Glenn v. B&R Plastics, Inc.*, 326 F. Supp. 3d 1044, 1062 (D. Idaho 2018). In their response to Defendants' motion for summary judgment, Plaintiffs failed to include any argument in opposition to Defendants' assertions aside from asserting they have satisfied the *prima facie* case to an action in products liability.

However, as set forth fully above, the Court has found Plaintiff has failed to establish such elements and to raise a genuine issue of material fact regarding the presence of reasonably likely alternative causes of Mr. Grunig's bowl obstruction. For this reason, the Court will also grant Defendants' motion for summary judgment as to Plaintiffs' failure to warn claims set forth in Claim Three and the relevant attendant portion of Count Four.

C. Negligence-based Claims

As indicated above, in Count Four of the Complaint, Plaintiffs assert Defendants breached "a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings" for the Ethicon Proceed surgical

mesh. (Dkt. 1 at 14.) Defendants argue Count four is simply a "re-packaging" of Counts One through Three. The Court agrees. To be clear, because the Court found Plaintiffs failed to raise a genuine issue of material fact to support their products liability actions for defective design, manufacture, or warning, the Court will also grant summary judgment as to all aspects of Count Four.

D. Loss of Consortium Claims

In Count Five, Plaintiffs assert Shannon Grunig has suffered a loss of her husband's consortium, due to the injures alleged related to the Ethicon Proceed Surgical Mesh. However, as the Court has found summary judgment is warranted as to all claims related to Mr. Grunig's bowl obstruction, the loss of consortium claim fails as a matter of law. *Zaleha v. Rosholt, Robertson & Tucker, Chtd.*, 953 P.2d 1363, 1365 (Idaho 1998) (A loss of consortium claim is necessarily dependent on success of the underlying claim of physical injury.).

CONCLUSION

The statements allegedly made by Dr. Fredline to Craig Grunig are hearsay and no hearsay exception applies, therefore the Court did not consider the statements as part of its consideration of the present motion for summary judgment. To that end, Plaintiffs failed to meet their burden to identify facts

showing a genuine issue for trial sufficient to defeat Defendants' motion for summary judgment as to all claims.

ORDER

IT IS ORDERED that

(1) Defendants' Motion to Strike (Dkt. 31) is **GRANTED**.

(2) Defendants' Motion for Summary Judgment (Dkt. 26) is **GRANTED in FULL**.

DATED: December 16, 2019

B. Lynn Winmill
U.S. District Court Judge