UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

STEVEN R. ERGLER, an individual, Plaintiff, v. JOHNSON & JOHNSON, a New Jersey corporation; ETHICON, INC., a New Jersey corporation; ETHICON ENDO-SURGERY, an Ohio corporation; ETHICON US, LLC, a Texas limited liability company, and DOES 1-10, Defendants.	No. **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY**

Plaintiff Alleges as follows:

INTRODUCTION

1. On March 18, 2019, the US Food and Drug Administration (the "FDA") sent a "Letter to Health Care Providers" regarding "Safe Use of Surgical Staplers and Staples" ("FDA Letter"). *See* https://www.fda.gov/medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers (accessed 7/2/2019).

2. The FDA Letter states that the FDA, between January 1, 2011, and March 31, 2018, received "over 41,000 individual medical device reports for surgical staplers and staples for internal use," which showed 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions.

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3. The FDA Letter states that some of the "most commonly reported problems in these adverse event reports" included "opening of the staple line or malformation of staples" and "misfiring."

4. Plaintiff Steven Ergler ("Plaintiff") underwent a laparoscopic sigmoid colectomy surgery on July 3, 2016, at a hospital in Vancouver, Washington. An Ethicon Endo-Surgery surgical stapler was used to perform the "anastomosis" portion of the surgery.

5. On the second post-operative day (July 5, 2016), Plaintiff had become progressively tachycardic, his hemoglobin had dropped, and a CT scan showed he had a significant amount of free air and fluid in the abdomen, significant for some sort of perforation.

6. During an exploratory laparotomy conducted on the second post-operative day (July 5, 2016), Plaintiff's surgeons did an "air test" showing that "there was a huge air leak and in fact the entirety of the back wall was completely blown out." The surgeons then "picked out several staples which were uncrimped to completely open, indicating that the stapler had completely misfired." The misfire had caused the failed anastomosis.

7. After repairing the anastomosis, the surgeon performed a diverting loop ileostomy. Since that time, Mr. Ergler's quality of life has been reduced. He has suffered several hernias, caused by the failed anastomosis, as well as daily pain, dysfunction, and humiliation.

PARTIES

8. Plaintiff is a Washington state resident. At the time of the injury that is the subject of this lawsuit, which occurred in Clark County, Washington, he resided in Lewis County, Washington.

9. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation headquartered in New Jersey. In 1947, it acquired a company that it renamed Ethicon Suture Laboratories. In 1953, this became Defendant Ethicon, Inc. ("Ethicon"). Defendant Ethicon, Inc., is a New Jersey Corporation headquartered in New Jersey. In 1992, Ethicon was restructured, and Defendant Ethicon Endo-Surgery, Inc. ("Ethicon Endo-Surgery"), became a separate Ohio Corporation headquartered in Cincinnati, Ohio. In 2013, J&J merged Ethicon Endo-Surgery back into Ethicon. Ethicon Endo-Surgery is now a subsidiary of Ethicon, Inc., which is a subsidiary of

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J&J, which has no parent company. Ethicon, US LLC is a business organized under the laws of the State of Texas and a wholly owned subsidiary of Johnson & Johnson. These defendants are collectively referred to as the "Ethicon Defendants."

10. At all relevant times, the Ethicon Defendants manufactured, marketed, and sold a product called the Ethicon Surgical Stapler, including Product No. ECS29A, which they labeled as a "29mm Endoscopic Curved Intraluminal Stapler." This product is hereafter referred to as "the Ethicon Stapler." It was the stapler that malfunctioned during Plaintiff's July 3, 2016, surgery.

11. On information and belief, the Ethicon Defendants are, and, at all relevant times, were, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, including in the State of Washington, either directly or indirectly through third parties or related entities, its products, including the Ethicon Stapler that was used to perform the anastomosis in Plaintiff's surgery.

12. On information and belief, J&J participated in, controlled, knew about, and approved of the other Ethicon Defendants' conduct in the development, design, sales, and marketing of the Ethicon Stapler. Defendant Ethicon and Ethicon US, LLC, controlled, knew about, and approved of, Ethicon Endo-Surgery's conduct in the development, design, sales, and marketing of the Ethicon Stapler. Defendants Ethicon and Ethicon US, LLC, are liable for the tortious conduct of Defendant Ethicon Endo-Surgery. Defendant J&J is liable for the tortious conduct of all other Ethicon Defendants.

13. The Court has personal jurisdiction over the Ethicon Defendants because the Ethicon Defendants, individually and/or acting in concert, presently and during the time of Plaintiff's surgery regularly did business in the state of Washington, such that they reasonably could expect to have to defend themselves in a Washington court.

14. Unknown Defendants listed as Does 1-10 are entities engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, including in the State of Washington,

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either directly or indirectly through third parties or related entities, the surgical stapler used perform the anastomosis in Plaintiff's surgery.

JURISDICTION AND VENUE

15. The amount in controversy exceeds $75,000, exclusive of interest and costs.

16. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 (Diversity of Citizenship).

17. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

18. Venue is proper under 28 U.S.C. § 1391 because Defendants, one or all of them, are subject to the Court's personal jurisdiction in this judicial district with respect to this civil action.

FACTUAL BACKGROUND

19. As of May 2016, Plaintiff suffered from symptoms of diverticulitis.

20. As of July 3, 2016, Plaintiff's doctor concluded, based on review of a CT scan, that he had mild sigmoid diverticulitis without perforation.

21. On July 3, 2016, Plaintiff's doctors performed a laparoscopic sigmoid colectomy with lighted ureteral stent.

22. According to the July 3, 2016, procedure note, during the procedure Plaintiff's doctors brought the end of his bowel up through a port site and removed the problematic portion of Plaintiff's bowel. The procedure note then states:

> The purse-stringer device was then used. We determined that a 29 EEA fit nicely. The end of the anvil was placed within the proximal bowel. This was then dropped back in. We reinsufflated, Allison went below. We dilated up the rectum, 29 fit nicely. The EEA stapler[1] was brought up through the rectum all the way to the end of the staple line. We deployed the pin through the middle of the staple line. The 2 ends of the stapler [were] placed and the anastomosis created in standard fashion. It was very nice. The stapler was removed. The donuts were very nicely intact and thick. We then did an air test. There was no leakage noted.

[1] As noted below, "EEA stapler" refers to the class of surgical staplers that are "end-to-end Anastomosis" staplers. The Ethicon Stapler is an end-to-end anastomosis stapler, and the billing records show that a size 29 Ethicon Stapler was used in the surgery.

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> Everything appeared to be within normal limits. At this point, we irrigated the pelvis. There was no bleeding.

23. By July 5, 2016 (postop Day 2), Plaintiff had become progressively tachycardic, his hemoglobin had dropped, and a CT scan showed he had "a significant amount of free air and fluid in the abdomen, significant for some sort of perforation." That day, his doctors started an exploratory laparoscopic procedure, then converted to an open exploratory laparotomy "with redo of the sigmoid rectal anastomosis and diverting loop ileostomy." During this procedure his doctors saw "a large amount of blood clot." The procedure note then reports:

> Once inside, I was able to visualize that there was a large amount of blood clot. I was able to suction out most of this. I went down towards the pelvis. There was a large amount of clot down there. Once I was down there, I visualized the anastomosis, it looked a little bit funny. I was not sure whether this was intact. I could not really tell. Therefore, my partner went below and we did an air test of anastomosis to ensure that it was completely intact. When he did this, we visualized that there was a huge air leak and in fact the entirety of the back wall was completely blown out. I also took pictures. There appeared to be uncrimped staples from the EEA stapler that had not crimped down, therefore creating a defect in the staple and a breech in the anastomosis.

24. At this point, according to the July 5, 2016, procedure note, Plaintiff's doctors converted to an open (non-laparoscopic) surgical procedure. During this portion of the procedure, Plaintiff's doctors reported: "The anastomosis was indeed completely opened in the entirety of the back wall. I picked out several staples which were uncrimped to completely open, indicating that the stapler had completely misfired."

25. After repairing the anastomosis, Plaintiff's doctors performed a diverting loop ileostomy.

26. A progress note dated July 19, 2016, states: "The patient's postoperative recovery was long and arduous. It included respiratory failure with adult respiratory distress syndrome. It also involved the development of Klebsiella bacteremia."

27. Since the failed anastomosis, Plaintiff's quality of life has been reduced. He has suffered several hernias and subsequent surgical and medical procedures, caused by the failed anastomosis, as well as daily pain, disability, and humiliation. His mobility has been significantly hampered.

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28. Plaintiff's medical bills from the service date "7/3/16" show a charge of $806.30 for one "STAPLER INTRALUMINAL CVD 29MM *ECS29A". "ECS29A" is the product code for the Ethicon Stapler.

29. The procedure notes from the 7/3/16 procedure state that a "29 EEA fit nicely" and refer to an "EEA stapler." "EEA stapler" refers to the class of staplers that are "end-to-end Anastomosis" staplers, and the Ethicon Stapler is an end-to-end anastomosis stapler. The Ethicon Stapler is offered in a 29 mm diameter size, and Ethicon also offers 29 mm sizers for use with the Ethicon Stapler. Ethicon's primary competitor in the EEA stapler market, Covidien, does not offer a size 29 EEA stapler.

30. The Ethicon Stapler was used to complete the anastomosis in Plaintiff's 7/3/16 surgery, and it malfunctioned.

31. As set out in the FDA Letter, in May 2019, the FDA identified an Ethicon recall of circular staplers as a Class I recall, the most serious type of recall. A Class I recall means use of the recalled device may cause serious injury or death. The reason for the recall given by Ethicon Endo-Surgery was that the Ethicon Stapler "may have an insufficient firing stroke to break the washer and completely form staples." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=171794 (Accessed 7/2/2019).

32. As of July 3, 2016, and before, the Ethicon Defendants asserted in the "surgical stapling" portion of their product catalog:

> Reliable tissue repair is a critical factor for all surgery. That's why Ethicon has worked with surgeons worldwide to develop and refine our surgical staplers and cutters. Our surgical stapling portfolio addresses the issues of tissue thickness, ***staple line security***, and tissue tension to provide you solutions that are designed to enhance control ***and patient safety***.

See http://pdf.medicalexpo.com/pdf/ethicon/2016-ethicon-product-catalog/74984-154353-_27.html (emphasis added, accessed 7/2/19).

33. As explained below, the Ethicon Stapler sold for use in Plaintiff's surgery did not provide "Reliable tissue repair," "staple line security," nor "enhance … patient safety."

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34. As of July 3, 2016, and before, the Ethicon Defendants asserted in the "Ethicon Intraluminal Circular Staplers" portion of their website that the Ethicon Stapler was "Reliable" and that it would reliably deliver "audible and tactile feedback indicating the firing sequence is complete[.]" *See* https://web.archive.org/web/20160628121552/http:/www.ethicon.com/healthcare-professionals/products/staplers/circular/circular-intraluminal (Accessed 7/2/19).

35. As explained below, the Ethicon Stapler sold for use in Plaintiff's surgery was not "Reliable" and did not reliably complete the firing sequence, despite the audible and tactile feedback given to Plaintiff's surgeon.

36. According to the FDA's Manufacturer and User Facility Database (MAUDE), from January 5, 2009, to July 3, 2016, the Ethicon Defendants received over 300 reports of injury and malfunction related to its curved intraluminal staplers. These included complaints that the staples had not crimped/formed completely. In fact, one event, just six months before Plaintiff's surgery, and involving the precise model used on Plaintiff, was remarkably similar to what happened to Plaintiff:

> "PATIENT WAS TAKEN TO THE MAIN OR FOR A LAPAROSCOPIC LOW ANTERIOR RESECTION. DURING THE RESECTION WHILE CREATING THE ANASTOMOSIS, THE SURGEON FIRED THE ETHICON 29 MM STAPLER. AFTER THE STAPLER WAS FIRED, THE SURGEON DID A ROUTINE LEAK TEST. DURING THE LEAK TEST, THE ANASTOMOSIS WAS "CRIMPED AND HAD A HOLE." THE SURGEON FELT IT WAS A RESULT OF THE STAPLER MISFIRING. THEREFORE, AN OSTOMY HAD TO BE CREATED."

See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=5483022&pc=GDW (Accessed 7/2/19).

37. This number of adverse events is likely only a small percentage of the actual number of malfunctions of Ethicon Staplers, as it is widely recognized in the medical device industry and by the FDA that the MAUDE database contains only a small fraction of the actual number of adverse events reported to the FDA.

38. The following are "customs in the product seller's industry," within the meaning of RCW 7.72.050(1), with respect to the medical device industry:

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a. The potential hazards of a product should be identified in the design phase and mitigated as much as possible.

b. A manufacturer of surgical staplers should never expose a patient to unnecessary risk of harm.

c. Safe control of an identified hazard involving serious injury or death requires that instructions or warnings be used only where the hazard cannot be engineered out or machine guarded against.

d. If, after a product is sold to consumers, a manufacturer learns that the product is capable of causing serious injuries or death, that manufacturer's engineers should investigate all incidents in which injuries and deaths were caused, and all incidents in which injuries or death could have been caused but were avoided by good fortune.

e. Information about serious injuries and deaths in the use of similar products made by others should also be investigated.

f. Once a hazard that threatens serious injury or death is identified affirmative steps must be taken to control the hazard.

g. Safe design of surgical staplers requires taking into account the performance characteristics of the device.

h. Safe design of surgical staplers requires taking into account the behavior of operators during foreseeable use of the device.

i. Safe design of surgical staplers requires taking into account the environmental factors, including foreseeable patient conditions, involved in the foreseeable use of the device.

j. Any solutions to safety issues revealed by field use of a device must be tested and evaluated to see if they work before they are implemented, and then monitored when used in the field to make sure they are in fact a solution.

k. A device must perform as safely as an ordinary user would expect.

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l. Documentation and retention of all hazard identification and any determination of whether or not to take steps to control an identified hazard is a necessary safety practice.

39. On information and belief, the Ethicon Defendants did not comply with one or more of these industry customs. Had they done so, Plaintiff would not have been injured by a defective Ethicon Stapler.

40. 21 CFR 820 is an "administrative regulatory standard" within the meaning of RCW 7.72.050(1) applicable to the Ethicon Defendants and the Ethicon Stapler.

41. The requirements of 21 CFR 820 include:

a. "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part." 21 CFR 820.5.

b. "Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications." 21 CFR 820.70(a).

c. "Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action." 21 CFR 820.100(a). These are referred to as "CAPA" procedures.

d. The CAPA procedures must include requirements for: "Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems." 21 CFR 820.100(a)(1).

e. The CAPA procedures must include requirements for: "Investigating the cause of nonconformities relating to product, processes, and the quality system[.]" 21 CFR 820.100(a)(2).

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f. The CAPA procedures must include requirements for: "Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems[.]" 21 CFR 820.100(a)(3).

g. The CAPA procedures must include requirements for: "Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device[.]" 21 CFR 820.100(a)(4).

h. The CAPA procedures must include requirements for: "Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems[.]" 21 CFR 820.100(a)(5).

i. The CAPA procedures must include requirements for: "Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems[.]" 21 CFR 820.100(a)(6).

j. The CAPA procedures must include requirements for: "Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.[.]" 21 CFR 820.100(a)(7).

k. All required CAPA activities, and their results, "shall be documented[.]" 21 CFR 820.100(b).

42. On information and belief, the Ethicon Defendants did not comply with one or more of the requirements of 21 CFR 820. Had they done so, Plaintiff would not have been injured by a defective Ethicon Stapler.

CAUSE OF ACTION
VIOLATION OF THE WASHINGTON PRODUCT LIABILITY ACT

43. Plaintiff realleges and incorporates every allegation of this Complaint as if each were set forth fully herein.

44. The Ethicon Stapler was defective within the meaning of the Washington Product Liability Act, RCW 7.72.

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45. The Ethicon Stapler was not reasonably safe in construction because it deviated in a material way from the design specifications or performance standards of its manufacturer.

46. The Ethicon Stapler was defective in construction and/or design because it was unreasonably dangerous the extent contemplated by the ordinary consumer with ordinary knowledge regarding the device.

47. At the time of Plaintiff's injuries, the Ethicon Stapler was defective in design because, at the time it was manufactured, the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage, outweighed the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.

48. The Ethicon Stapler was not reasonably safe because adequate warnings or instructions were not provided with the product.

49. The Ethicon Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers as to the safest and most effective methods of use of the stapler used to perform Plaintiff's anastomosis on July 3, 2016.

50. The Ethicon Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers, including Legacy Salmon Creek Medical Center, as to the risks and benefits of the Ethicon Stapler, given the Plaintiff's conditions and need for information.

51. To the extent the Ethicon Defendants were obligated to, or undertook to, train Plaintiff's health care providers in the use of the Ethicon Stapler the training was inadequate.

52. Pursuant to *Taylor v. Intuitive Surgical, Inc.*, 187 Wash.2d 743, 389 P. 3d 517 (2017), Comment K to Restatement (Second) § 402(a) does not apply to defective construction, marketing, or warning claims. Rather, "proper preparation, marketing, and warnings are prerequisites to a manufacturer being able to qualify for this exception to strict liability . . . . To apply the standard of the exception before its prerequisites have been met would allow the exception to swallow the rule." *Id.* at 762.

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53. To the extent Comment K to Restatement (Second) § 402(a) applies to the defective design claim, the Ethicon Defendants failed to use reasonable care to design a medical product that was reasonably safe.

COMPENSATORY DAMAGES

54. Plaintiff realleges and incorporates every allegation of this Complaint as if each were set forth fully herein.

55. Plaintiff intends to claim every category of compensatory damages available to him, as set out in WPI Chapters 30, 32 and 34. The conduct that makes the Ethicon Defendants liable to Plaintiff also was a proximate cause and/or substantial factor in causing the following:

a. Plaintiff was injured, badly and permanently, and has sustained past and future pain; suffering; mental, physical, and emotional distress; disability; disfigurement; impairment; humiliation; fear; and loss of enjoyment of life.

b. Plaintiff has incurred economic damages, including past and future medical and other expenses.

56. The amount of these damages will be proven at trial.

PUNITIVE DAMAGES

57. Plaintiff realleges and incorporates every allegation of this Complaint as if each were set forth fully herein.

58. While Washington law should apply to the compensatory damages claims, another State's law on punitive damages may apply in this case under the principles explained in *Singh v. Edwards Lifesciences Corp.*, 151 Wn. App. 137, 144, 210 P.3d 337 (2009) and *Taylor v. Intuitive Surgical, Inc.*, Kitsap County Superior Court No. 09-2-03136-5, Order and Memorandum Opinion on Defendant ISI's (1) Motion for Summary Judgment on All Claims and (2) Motion for Summary Judgment on the Issue of Punitive Damages (March 25, 2013) (Roof, J.) ("it is apparent that California has an interest in deterring activities that illustrate a 'conscious disregard of safety' of others, originating from corporations that have a 'substantial business

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presence within its borders.' Washington has no interest in shielding from liability individuals who partake in such activities.").

59. If, after adequate discovery, Plaintiff learns of facts showing that any Defendant's conduct justifies an award of punitive damages, Plaintiff will seek to amend this Complaint to add a claim for punitive damages under the law of the state wherein the conduct that justifies punitive damages occurred.

LIMITED WAIVER OF PHYSICIAN/PATIENT PRIVILEGE

60. Pursuant to RCW 5.60.060(4)(b), Plaintiff hereby waives the physician/patient privilege only insofar as necessary to place any and all alleged damages at issue at the time of trial, as might be required by statute or amended statute or case law interpreting the statutes of the State of Washington. It should be understood that Plaintiff's actions do not constitute a waiver of any of his constitutional rights and that the Defendants are not to contact any treating physicians without first notifying counsel for the Plaintiff so that they might bring the matter to the attention of the Court and seek appropriate relief, including imposing limitations and restrictions upon any desire or intent by the Defendants to contact past or subsequent treating physicians *ex parte*, pursuant to the rule announced in *Loudon v. Mhyre*, 110 Wn.2d 675, 756 P.2d 138 (1988) and *Smith v. Orthopedics International, Ltd., P.S.*, 170 Wn.2d 659, 244 P.3d 939 (2010).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper, as well as:

1. Compensatory damages to the Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff;
2. Health and medical care costs, together with interest and costs as provided by law;
3. Reasonable attorneys' fees;

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4. The costs of these proceedings; and

5. All ascertainable economic damages.

DATED this 2nd day of July 2019.

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