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ATTORNEYS FOR PLAINTIFF

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LORRAINE BONNER, Plaintiff, vs. COVIDIEN, LP., and MEDTRONIC, INC., Defendants	Case No.: COMPLAINT FOR DAMAGES **1. STRICT LIABILITY MANUFACTURING DEFECT** **2. STRICT LIABILITY DESIGN DEFECT** **3. STRICT LIABILITY-FAILURE TO WARN** **4. NEGLIGENCE** JURY TRIAL DEMANDED

Plaintiff, by and through her undersigned counsel, brings this Complaint for damages against Defendants and in support thereof states the following:

INTRODUCTION

1. Defendants, and each of them, designed, manufactured, and marketed without proper notice, defective Endo GIA surgical staplers. The FDA recently reported that during the time period from January 1, 2011 through December 31, 2018 it received close to 110,000 reports related to issues with surgical staplers. Of these 412 were submitted as deaths, 11,181 were

submitted as serious injuries, and 98,404 were submitted as malfunctions.[1] The numbers reported by the FDA were largely hidden from public view because the majority of the reports were not submitted to the Manufacturer and User Facility Device Experience, or MAUDE, a publically-accessible database run by the FDA, but instead, were submitted to the ASR Program. The ASR program enabled manufacturers of certain device types to submit quarterly summary reports of specific well known and well characterized events in lieu of individual reports of each such event that tracks medical device failures. Defendants, and each of them, used the ASR program to keep the scope of injuries related to surgical staplers hidden from surgeons and their patients.

2. Plaintiff Lorraine Bonner was injured when a surgical stapler, designed, manufactured, and marketed by Defendants, malfunctioned during her November 28, 2017 surgery, resulting in a leak in her bowel that had to be repaired through a second surgery.

JURISDICTION AND VENUE

3. This Court has diversity subject matter jurisdiction pursuant to 28 U.S.C. § 6 1332(a).

4. Venue is proper in this court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in this district.

5. Defendants have conducted, and continue to conduct, substantial business in the State of California and in this District; distribute Covidien Product in this District; receive substantial compensation and profits from sales of Covidien Product in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this district.

6. Covidien and Medtronic are both registered to transact business in California.

PARTIES

7. PLAINTIFF LORRAINE BONNER is and was, at all times herein relevant, a citizen and resident of Oakland, Alameda County, California.

8. Covidien, LP, ("Covidien") is a Delaware Limited Partnership and has its principal place of business in Mansfield, Massachusetts. Covidien manufactures, distributes, and services medical devices, including medical devices known as endo GIA surgical stapler.

[1] FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

9. Medtronic, Inc. ("Medtronic") is incorporated in Minnesota and has its principal place of business in Minneapolis, Minnesota. Medtronic is a medical device company involved in the design, manufacturing, marketing, packaging, labeling, and sale of medical devices.

10. In January 2015, Medtronic acquired Covidien. From that point forward, Medtronic has been responsible for the actions of Covidien, and exercised control over Covidien's functions specific to the oversight of compliance with applicable safety standards relating to and including the Covidien Product sold in the United States. In such capacity, Medtronic committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Medtronic's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

11. Covidien and Medtronic (collectively referred to as "Defendants") are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective Covidien Product at issue in this suit. All acts were effectuated directly and indirectly through Defendants' respective agents, servants, employees, and/or owners, acting within the course and scope of their representative agencies, services, employments, and/or ownership.

12. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all times relevant acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

DOE DEFENDANTS

13. Plaintiff does not know the true names and capacities, whether individual, corporate, associate, or otherwise of DEFENDANT Does 1 through 25 inclusive and therefore sues these Defendants by such fictitious names. Plaintiff will amend her complaint to allege their true names and capacities when this has been ascertained.

RESPONDENT SUPERIOR

14. All of the described conduct, acts, and failures to act are attributed to agents and employees under the direction and control, and with the permission, consent and authorization of

DEFENDANTS. Said acts, conduct and failures to act were within the scope of such agency and/or employment, and each DEFENDANT ratified the acts and omissions of each of the other DEFENDANTS. Each of these acts and failures to act is alleged against each DEFENDANT whether acting individually, jointly, or severally. At all times relevant herein, each DEFENDANT was acting within the course and scope of his or her employment.

STATEMENT OF FACTS

15. On or about November 28, 2017 Plaintiff underwent a sigmoidectomy with primary anastomosis of left colon to distal sigmoid. During the procedure, damaged colon tissue was removed. A distal transection was performed, with healthy tissue connected using a Coviden endo GIA purple load stapler.

16. Defendants, and each of them, were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of the endo GIA surgical stapler at issue in this lawsuit.

17. Plaintiff alleges on information and belief that the specific stapler used in her November 28, 2017 surgery was a model, known by Defendants, to frequently malfunction. In May 2018, Defendant Medtronic issued a recall on endo GIA staplers. Additionally, as recently as June 3, 2019, Defendant Medtronic issued a second recall on its endo Gia surgical staplers, including staplers that were distributed between April 2014 and April 2019. Plaintiff alleges on information and belief that the stapler used in her surgery was included in one or both of the recalls.

18. Prior to using the endo GIA stapler, the abdomen was irrigated thoroughly. The surgeon assessed the bowel tissue and determined that the tissue was healthy enough to re-connect the bowel without the need for an ostomy. Prior to the surgery, the surgeon indicated that an ostomy might be required if the bowel tissue was not healthy enough to reconnect. The ostomy would be needed for a short period of time while the tissue healed. However, during the surgery, after assessing the tissue health, the surgeon determined that an ostomy was not necessary.

19. Thereafter, the colon was fully mobilized and confirmed tension free. The surgical connection was leak-tested. Initially a small leak was noted, but surgeons were unable to replicate

the leak. The area was reinforced after which the connection was leak-tested multiple times without evidence of leak.

20. After the procedure, Plaintiff was slow to regain bowel function and experienced nausea and vomiting. Plaintiff was not able to eat and therefore was not able to be discharged from the hospital after the November 28, 2017 surgery. Plaintiff's condition began to worsen. Plaintiff's drain started having bilious fluid. On December 6, 2017, Plaintiff was brought back to the operating room with suspicion of bowel leak.

21. On December 6, 2017, Plaintiff underwent a second surgery, necessitated by a bowel leak caused by the defective surgical stapler. During the second surgery, a colon leak was detected. The second surgery resulted in further colon resection and an appendix resection. The leak was caused by Defendants' defective stapler.

22. As a result of the defective stapler, Plaintiff was forced to undergo three additional surgical procedures. The first was the emergency surgery on December 6, 2017 to address sepsis that resulted from the bowel leak. As a result of this surgery, Plaintiff incurred additional medical expenses, prolonged her hospital stay, and suffered significant physical, mental and emotional suffering.

23. After the second surgery, plaintiff was required to use a colostomy bag for a period of time until she had a third surgery to remove the colostomy bag. The use of the colostomy bag caused Plaintiff to suffer severe physical, mental and emotional injury. After the removal of the colostomy bag, Plaintiff suffered incisional hernias, which required a fourth procedure to correct.

24. Plaintiff has since learned that the stapler in question was likely recalled and that the FDA recently reported that surgical staplers, including those manufactured by Defendants, have been responsible for tens of thousands of adverse outcomes attributed to malfunctioning staplers.

25. In the FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel[2], the FDA included the following example of a common result of a defective surgical stapler: "For example, an early postoperative anastomotic leak resulting from stapler malfunction may lead to sepsis due to peritonitis, requiring immediate surgery with

[2] Id.

diversion of the stool through a cutaneous stoma. Such stomas require a second operation to reverse, but are frequently not reversed leaving the patient with a permanent stoma and the related quality of life issues. The stomas that are reversed may themselves result in a leaking anastomosis or an incisional hernia, also prolonging the patient's compromised quality of life and ability to be productive."[3] This example exactly describes Plaintiff's experience.

26. Defendants, and each of them, have taken advantage of FDA exemptions and have refused and failed to report non-fatal stapler related injuries to the MAUDE. Instead, Defendants, and each of them, have utilized an alternative summary reporting program, which is not publically accessible. By not reporting all stapler-related injuries on MAUDE, Defendants have hidden the true risks of the using the devices from surgeons and their patients. For example, in 2016, while reports of 84 stapler injuries or malfunctions were openly submitted, nearly 10,000 malfunctions reports were included in the hidden database, according to the FDA.[4]

27. Though Defendants, and each of them, attempted to keep the number of stapler related injuries hidden from medical professionals, in surveys of surgeons conducting surgeries with surgical staplers, up to 73% reported personal experience of, and 86% reported knowing of someone experiencing stapler misfire or malfunction during surgery.

28. The public Database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001.[5] Despite this knowledge of the dangers associated with using its products, Medtronic used reporting exemptions to file stapler-related reports in a database hidden from doctors and from public view through July 2017.[6] By doing so, Defendants intentionally concealed from public view the many injuries caused by the use of its endo Gia staplers. This concealment denied surgeons, including the surgeon who performed Plaintiff's surgery, and patients like Plaintiff, critical information on the safety of its products.

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[3] FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

[4] *Hidden FDA Reports Detail Harm Caused By Scores Of Medical Devices*, https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/

[5] Id.

[6] Id

29. Based on the number of stapler-related injuries, in May 2019, the FDA proposed reclassifying surgical staplers for internal use from Class I to Class II (Special Controls).[7] Further, device manufacturers are no longer able to use the reporting exemptions for injuries related to surgical staplers. As a result, reports by Defendant Medtronic, related to malfunctions or injuries related to the Covidien staple, skyrocketed from 1,000 reports in 2015 to 11,000 reports in 2018.

30. Despite knowing that its endo GIA staplers caused injuries due to malfunction, Defendants, and each of them, represented and marketed the endo GIA staplers as safe and effective. Defendants, and each of them, failed to include warnings regarding potential malfunctions that were known to them, including the risks described in the FDA publication.[8]

31. Defendants intentionally engaged in the following conduct: 1) failing to provide warnings regarding the potential for its endo GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 2) failing to warn and inform surgeons of the potential for its endo GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 3) failing to recall its defective products until 2018 and 2019 when it knew earlier that endo GIA surgical staplers were prone to malfunction; 4) failing to publicly report each endo GIA surgical stapler malfunction or injury in the publicly accessible database and thereby conceal know incidents from public view. By engaging in the conduct described above, Defendants engaged in willful, wanton, reckless, malicious behavior and/or exhibited a gross indifference to, and a callous disregard for human life, the safety and the rights of others, and more particularly, the rights, life and safety of the Plaintiff; and Defendants were motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement and cost avoidance, to the virtual exclusion of all other considerations.

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FIRST CAUSE OF ACTION

[7] FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

[8] Id. at pg 9.

(STRICT LIABILITY MANUFACTURING DEFECT)
Against all DEFENDANTS

32. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

33. Plaintiff was harmed by Defendants' defective endo GIA surgical stapler, which was distributed, manufactured, and sold by Defendants. Defendants' endo GIA surgical stapler contained a manufacturing and design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in an anastomotic leak despite proper utilization by a surgeon.

34. As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

35. Due to Defendants' negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

SECOND CAUSE OF ACTION
(STRICT LIABILITY DESIGN DEFECT)
Against all DEFENDANTS

36. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

37. Plaintiff was harmed by Defendants' defective endo GIA surgical stapler, which was distributed, manufactured, and sold by Defendants. Defendants' endo GIA surgical stapler contained a manufacturing and design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in an anastomotic leak despite proper utilization by a surgeon.

38. As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment

of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

39. Due to Defendant's negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

THIRD CAUSE OF ACTION
(STRICT LIABILITY-FAILURE TO WARN)
Against all DEFENDANTS

40. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

41. Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their endo GIA staplers. Specifically, Defendants, and each of them, promoted the staplers as being safe while they used FDA reporting exemptions to avoid publicly disclosing known incidents where endo GIA staplers injured patients due to malfunctions. As a result, neither Plaintiff nor her surgeon knew of the risks of injury like the one Plaintiff suffered, prior to her surgery.

42. Defendants, and each of them, knew that the endo GIA stapler posed a risk to patients when used as intended because certain units were manufactured without a component that resulted in a failure to form a staple line that resulted in leakage.

43. Despite knowing about this defect, Defendants, and each of them, failed to warn potential surgeons or patients until an initial recall in 2018 and a second recall in 2019. The 2019 recall included devices that were distributed between April 2014 and April 2019. Plaintiff's surgery was in 2017.

44. As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including

additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

45. Due to Defendants' negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

FOURTH CAUSE OF ACTION
(NEGLIGENCE)
Against all DEFENDANTS

46. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

47. Plaintiff's injuries associated with having a second and third surgery were all the result of Defendants' defective endo GIA surgical stapler.

48. At all times herein relevant, Defendants, and each of them, were in the business of designing, manufacturing, assembling, constructing, inspecting, and selling various types of medical devices, including the subject endo GIA stapler. Defendants were further in the business of inspecting, maintaining, installing and selling at retail to members of the public various types of medical devices designed and manufactured by Defendants, including the subject endo GIA stapler.

49. At all times herein relevant, Defendants so negligently and carelessly designed, manufactured, constructed, assembled, inspected, and/or sold the subject endo GIA surgical stapler that it was dangerous and unsafe to be used for its intended uses.

50. Furthermore, at all times relevant to this action, Defendants so negligently and carelessly inspected, maintained, installed, and sold the subject endo GIA surgical stapler that it was dangerous and unsafe for its intended uses.

51. Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the subject endo GIA surgical stapler device that was used on Plaintiff.

52. At all times herein relevant, Defendants knew or reasonably should have known that the subject endo GIA surgical stapler was unreasonably dangerous and defective when used as directed and designed, including but not limited to its failure to create staple lines leading to anastomotic leaks and other complications and injuries.

53. Based on what Defendants knew or should have known as described above, Defendants deviated from the standard of care and were negligent in introducing the endo GIA surgical stapler, which was unreasonably dangerous and defective when used as directed and designed, into the stream of commerce.

54. Further, Defendants were negligent for not providing sufficient notice or warnings of the risks associated with using the endo GIA surgical stapler, including the risks associated with malfunction.

55. The injuries and damages suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

56. As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

PRAYER FOR RELIEF

1. For special and economic damages, including lost wages, for all Causes of Action;
2. For general and non-economic damages for all Causes of Action;
3. For punitive damages for all Causes of Action;
4. For prejudgment interest at the prevailing legal rate;
5. For costs of the suit including reasonable attorney's fees; and
6. For such other and further relief, including injunctive relief, as the Court may deem proper.

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Dated: September 19, 2019

RESPECTFULLY SUBMITTED,
LAW OFFICES OF BONNER & BONNER

/s A. Cabral Bonner
A. Cabral Bonner
Attorney for Plaintiff

JURY TRIAL DEMANDED

Dated: September 19, 2019

RESPECTFULLY SUBMITTED,
LAW OFFICES OF BONNER & BONNER

/s A. Cabral Bonner
A. Cabral Bonner
Attorney for Plaintiff