IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY BELL Plaintiff, v. COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDING INC., and MEDTRONIC, INC., Defendants.	**CIVIL ACTION** Case No. COMPLAINT AND JURY DEMAND

COMPLAINT AND JURY DEMAND

COME NOW Plaintiffs KIMBERLY BELL, by and through her undersigned counsel, who hereby files this Complaint and states as follows:

INTRODUCTION

1. Defendants, and each of them, designed, manufactured, tested marketed, distributed, and sold, without proper warnings, defective Circular and Linear staplers used internally for surgical procedures.

2. Plaintiff, Kimberly Bell, was injured when a defective surgical stapler [Endo GIA 45mm with Tri Staple Technology (EGIA45AVM), and/or the Covidien Endo GIA 60mm with Tri Staple Technology (EGIA60AVM), and/or the Covidien Endo GIA Universal XL (EGIAUXL)], designed, manufactured, tested, marketed, and sold by Defendants, malfunctioned during a surgical procedure that occurred on or about September 11, 2019. The defective device caused a "tear" of Ms. Bell's tissue in the surgical area, requiring had to be repaired through additional surgeries to repair the injured tissue, and treated with prolonged hospitalization and extensive medical care. Ms. Bell's condition requires medical monitoring to this day.

PARTIES, JURISDICTION & VENUE

3. Plaintiff Kimberly Bell, a single woman, is and, at all times relevant, a resident and citizen of the State of North Carolina.

4. Defendant Covidien LP is a Delaware Limited Partnership with its principal place of business in Massachusetts. It is the single member of Covidien Sales LLC, a Delaware limited liability company with its principal place of business in Massachusetts. Covidien LP has one general partner: Covidien Holding Inc., a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien LP is involved in the design, testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers at issue in this case.

5. Defendant Covidien Holding Inc. is a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien Holding Inc. is involved in the testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers at issue in this case.

6. Defendant Covidien Sales LLC is a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien Sales LLC is involved in the design, testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical stapler reloads at issue in this case.

7. Defendant Medtronic, Inc., is a Minnesota corporation with its principal place of business in Minnesota. Among its business activities, Medtronic, Inc., is involved in the design, testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers at issue in this case.

8. All acts and omissions of Defendants as described herein were done by their agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

9. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that there is complete diversity between Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

10. Defendants have significant contacts with this federal judicial district and operates its surgical stapler systems' design, manufacturing, and marketing business in this federal district such that it is subject to the personal jurisdiction of the Court in this district.

11. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

FACTS COMMON TO ALL COUNTS

Device failure and injuries

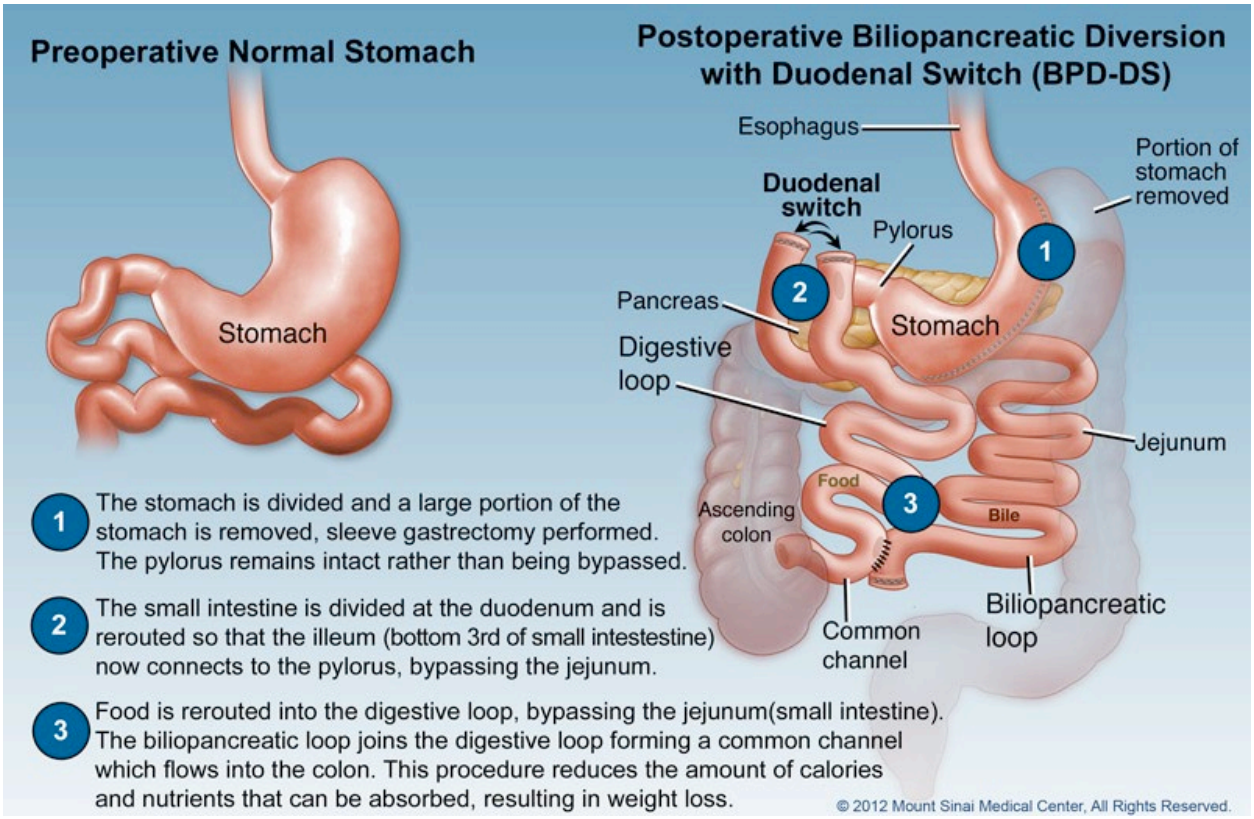
12. Plaintiff Kimberly Bell's physician, Peter Ng, M.D. concluded Ms. Bell was in sufficient health to undergo a surgical procedure defined by her doctor as a Laparoscopic Biliopancreatic Diversion with Duodenal Switch, and Laparoscopic Hiatal Hernial Repair on September 11, 2019. This procedure is used to assist a patient in achieving weight loss goals.

13. A Laparoscopic Biliopancreatic Diversion with Duodenal Switch is a two-step procedure where a surgeon makes tiny openings in a person's belly and inserts a small camera to guide the procedure which uses surgical instruments to first cut, separate, and remove 80% of the patient's stomach. The remaining "sleeve-like" section of the stomach is open until it is sealed. The section that releases food into the small intestine (called the pyloric valve) remains, along with a limited

portion of the small intestine that normally connects to the stomach (called the duodenum). Then the majority of the intestine is bypassed by connecting the end portion of the intestine to the duodenum near the stomach[1].

14. Physicians can use a surgical stapler device, such as Covidien's Endo GIA stapler, to staple the open stomach shut. A staple line failure occurs when a device fails to deploy staples that seal the stomach, allowing the stomach's bacteria ridden contents to empty into the patient's sterile body cavity.

Figure 1



15. On September 11, 2019, Plaintiff underwent a Laparoscopic Biliopancreatic Diversion with Duodenal Switch, and Laparoscopic Hiatal Hernial Repair. Dr. Ng used a Covidien Endo

[1] Biliopancreatic diversion with duodenal switch (BPD/DS) - Mayo Clinic *See also* video of procedure on this site.

GIA stapler to seal, separate a section of the Plaintiff's stomach, and create the duodenoileal anastomosis. Dr. Ng's performed the procedure consistent with standard medical practices.

16. At all times during the procedure, Dr. Ng used the surgical stapler in accordance with Defendants' training materials and did not deviate from Defendants' recommended Instructions for Use included in the device's package insert.

17. The procedure was performed by using an Endo GIA device which is inserted in the abdomen area using a "Trocar" (tunneling device). Once inside the stomach area and a gastric sleeve is created, cut, and stapled to seal the stomach shut, then the duodenal switch is completed (see Figure 1, *supra*).

18. Because it is impossible for a physician to confirm a staple line is properly sealed, a leak test can be performed to test whether the staple line has properly sealed the stomach. Dr. Ng performed a leak test, which appeared patent.

19. However, because a stapling device compresses delicate stomach tissue so tightly, often a leak test can fail to ensure staples have been properly deployed and formed a properly sealed staple line.

20. Only after several days when the patient begins to consume food and the digestive process exerts stress on a newly stapled stomach, does a physician know whether the stapler properly sealed a stomach, or a staple line failure has occurred, indicated by digestive contents leaking into nearby organs.

21. The removed stomach was sent to pathology and was observed to be healthy tissue which indicates a likelihood of proper healing of the remaining stomach tissue.

22. On September 13, 2019, Ms. Bell developed several episodes of nausea/vomiting and hypertension. On September 14, 2019, she developed shortness of breath and worsening

abdominal pain. A chest x-ray revealed pulmonary edema. Ms. Bell's abdominal pain had worsened, and she had poor urinary output.

23. On September 14, 2019, she also became hypotensive (low blood pressure) and diaphoretic (sweaty). A CT of the abdomen and pelvis without contrast showed a large amount of fluid in the abdomen and a moderate amount of free air. The overall impression was "[a] large amount of fluid raises concern for anastomotic leak." She was taken emergently to the operating room where she underwent repair of duodenoileostomy leak[2] (this is an anastomotic leak at the duodenoileostomy, the surgical formation of a passage between the duodenum and the ileum (see Figure 1, *supra*)), with modified graham patch, abdominal washout, drain placement, esophagogastroduodenoscopy, (referred to as an "EGD", which uses an endoscope (a flexible tube with a light and camera at the end) inserted through the esophagus to the stomach and duodenum (the first part of the small intestine)).

24. The duodenoileostomy was examined and a "small tear" at the apex staples, measuring 5 mm was noted. This "tear" was closed with 3 interrupted figure of eight sutures using 2-0 Vicryl suture; the leak was sealed.

25. This anastomotic leak led to Ms. Bell's development of acute respiratory failure and pulmonary edema leading to septic shock. After her procedure on September 14, 2019, Ms. Bell was transferred to the critical unit for medical intensive care and vent management, Ms. Bell was on a ventilator for seven (7) days. She required several liters of Lactated Ringer's solution[3] and developed acute kidney injury which required her to start intermittent hemodialysis.

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[2] [T]he incidence of leak at the duodenoileostomy was 0.6 percent (9/1328); Leaks and Single Anastomosis Duodenoileal Bypass with Sleeve Gastrectomy (SADI) : Bariatric Times, referencing Surve A, Cottam D, Sanchez-Pernaute A, et al. The incidence of complications associated with loop duodeno-ileostomy after single-anastomosis duodenal switch procedures among 1328 patients: a multicenter experience. Surg Obes Relat Dis. 2018;14(5):594–601

[3] Lactated Ringer's solution is an intravenous fluid that doctors use to treat dehydration and restore fluid balance in the body. The solution consists primarily of water and electrolytes. As an alkalizing agent, LR also helps reduce the

26. On September 17-18, 2019, Ms. Bell went into atrial fibrillation.

27. Seven (7) days after her second surgery, on September 21, 2019, Ms. Bell was extubated and transferred to a regular room on September 26, 2019.

28. Ms. Bell spent another fifteen (15) days in the hospital while she began occupation and physical therapies, her wounds healed, and the drains were removed.

29. Ms. Bell was discharged on October 11, 2019, thirty (30) days after her initial surgery.

30. Ms. Bell was admitted to the hospital for a total of thirty (30) days. She spent almost two weeks in critical care and on a ventilator for one week.

31. She developed kidney injury requiring hemodialysis (the process of purifying the blood when the kidneys are not functioning normally), a condition and treatment she had not had previously.

32. The complications suffered by Ms. Bell, indicated by the severity and numerosity of her diagnosis at discharge includes:

- Acute respiratory failure,
- Acute Kidney injury requiring dialysis
- Pulmonary edema leading to septic shock secondary to anastomotic leak;
- Anuria (non-passage of urine);
- Mechanical ventilation;
- Atrial fibrillation.

33. Ms. Bell's long overdue discharge was not to her home, but instead to an inpatient rehabilitation facility for approximately two (2) weeks.

34. When she was released home, Ms. Bell spent another approximate two (2) weeks with home health care.

levels of acidity within the body. Therefore, doctors may use the solution to treat high acid levels resulting from sepsis or other conditions Lactated Ringer's: Uses, side effects, and more (medicalnewstoday.com)

35. Defendants' defective stapler has caused Ms. Bell to suffer significant injuries, including permanent deleterious alterations to her quality of life caused by ongoing bowel issues requiring the need for immediate restroom use after eating or drinking, leading to many embarrassing accidents, and causing an increasing isolation and from her friends, family, and loved ones.

36. Since her 2019 surgery, Plaintiff has suffered physical and emotional injuries directly caused by the failed surgical stapler used during her surgery.

37. As a direct result of her injury caused by Defendants' failed stapler, Plaintiff did, and continues to incur, out of pocket expenses and suffers economic harm.

38. Plaintiff was not aware that the surgical stapler used during her September 11, 2019, procedure could fail and result in additional surgeries, extended hospital treatment, rehabilitation, home health care, chronic medical monitoring, and economic harm.

39. Had Plaintiff known that the surgical stapler device used on her during her procedure could fail and cause the injuries she suffered, she would not have consented to the elective procedure.

40. Had Plaintiff's physician known of the true failure rate of the Endo GIA stapler used on Ms. Bell during her surgery, he would not have performed the procedure and/or would not have used the Endo GIA device.

Surgical Staplers

41. Since the early 1900s, surgical staplers have been used in the medical community to assist in a number of medical operations and procedures.[4],[5]

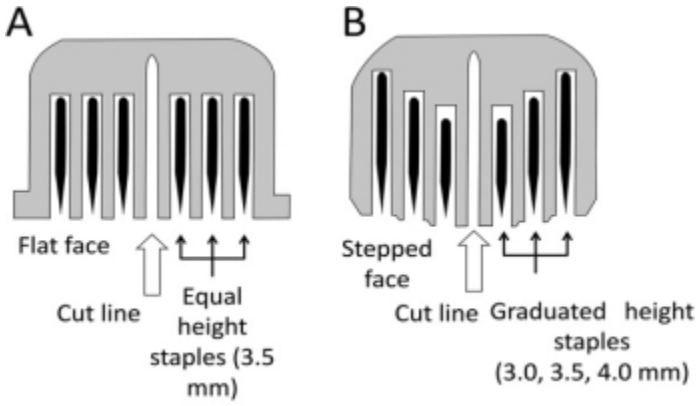
42. Typically, a stapler is comprised "of the stapler body, a staple cartridge/reload withlines of staplers, an anvil, and a firing mechanism. The surgeon loads a staple cartridge into the stapler

[4] *See* Sophie Childs, *Everything Healthcare Professionals Need to Know about Surgical Staples,* CIA (Apr. 18, 2017) https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about-surgical-staplers/.
[5] All footnoted documents will be made available upon request.

(unless they are using a preloaded device) before placing the tissue to be connected between the stapler jaws (comprising of the cartridge and anvil). They then activate a firing mechanism to shoot staples into place."[6]

43. Innovations in the manufacturing of surgical staplers have led to the creation of different categories of staplers to assist with specific procedures. Some of the categories are the Linear Stapler and the Circular Stapler. These staplers are used in general surgery as well as thoracic surgery, bariatric surgery, and colo-rectal surgery. Most staplers are categorized as either linear or circular. While circular staplers are often used in surgeries of the digestive tract and colon, linear staplers are used primarily to connect tissues or remove organs, such as the surgery performed on Ms. Bell. Typically, linear staplers fire two staggered rows of staples from a linear cartridge, which allows the stapler to connect two sections of tissue, after a portion has been cut. A built-in blade then cuts off the overlaying tissue, sealing the new connection. The stapler used in this case uses Defendants' Tri-Staple Technology which deploys staples in two triple-staggard rows at different heights (see Model B of Figure 2).

Figure 2



44. Surgical staplers for internal use have the primary function of delivering staples to tissues

[6] *Id.*

inside the body during both minimally invasive (laparoscopic) and open surgery when removing part of an organ (resection), cutting through and sealing organs and tissues (transection), or creating connections between structures (anastomoses).[7] The most significant benefit of surgical stapler use is that it permits a surgical procedure to be performed laparoscopically. In other words, large incisions are not necessary to perform these surgical procedures, because a surgical stapler device can fit into a small external tissue opening, requiring only minimal incisions at site entry.

45. The FDA has acknowledged that the advantages of using surgical staples and staplers include: "Quick placement; Minimal tissue reaction; Low risk of infection; [and] Strong wound closure."[8]

46. During the procedure in question, medical records document the following products manufactured by Defendants were used: Endo GIA 45mm with Tri Staple Technology (EGIA45AVM), the Covidien Endo GIA 60mm with Tri Staple Technology (EGIA60AVM), and the Covidien Endo GIA Universal XL (EGIAUXL). Upon information and belief, the specific surgical stapler that failed during Plaintiff's procedure, is the Covidien Endo GIA 45mm with Tri Staple Technology (EGIA45AVM), and/or the Covidien Endo GIA 60mm with Tri Staple Technology (EGIA60AVM), and/or the Covidien Endo GIA Universal XL (EGIAUXL). This stapler, tan reload, comes in staple sizes of 2.5, 2.5, and 3.0mm and is specifically designed for medium tissue; the tan reloads are available in 30mm, 45, mm and 60mm staple line lengths, and releases two triple-staggered rows of titanium staples and simultaneously divides the tissue between the two triple-staggard rows[9].

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[7] *Surgical Staplers and Staples*, FDA.GOV, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples (last updated October 7, 2021).
[8] *Id.*
[9] FDA 510(k) Summary of Safety and Effectiveness, number K101444, prepared May 21, 2010; K101444.pdf (fda.gov)

Surgical Stapler Failure and Malfunction

47. The risk of failure and malfunction of surgical staplers has been well-known to the Defendants since the start of the device's widespread use in the early 1990s and the figures pulled from these studies are startling. For example, by 2001, Defendants knew, or should have known, that 112 deaths, 2,180 injuries, and 22,804 adverse events (AEs) associated with device malfunction had been reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.[10] The sheer bulk of AEs should have signaled the Defendants that there was a defect in their product.

48. The pattern continued. In January 2006 to January 2016, there was a total of 13,312 reports, with 106 events resulting in death, 3,234 resulting in injury, and 9,972 involving a device malfunction.[11] To put these numbers into perspective, over this 10-year period 75% of all reported stapler-related events involved device malfunction, and more than 25% resulted in injury or death.

49. 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.[12] To make matters worse, over half of these adverse event reports were not submitted into MAUDE, but to a secret FDA database. This abuse of FDA policy to the extreme detriment of thousands of patients like Kimberly Bell will be discussed at length in another section. All of this information – from 2001 to 2019 – was known to Defendants.

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[10] S. Lori Brown, *Surgical Stapler-Associated Fatalities and Adverse Events Reported to the Food and Drug Administration*, 199 J. AM. COLL. SURG. 3, 374 (Sept. 2004)

[11] MK Riggs, *Examining Relationships Between Device Complexity and Failure Modes of Minimally Invasive Surgical Staplers*, 3 Biomedical and Biotechnology Engineering (Feb. 2017)

[12] *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*, FDA.GOV, https://www.fda.gov/media/126211/download (last updated July 2, 2019).

50. While 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 event that tracks medical device failures, the Program did not discharge all duties imposed on manufacturers by Federal Regulations[13] to report device related events to the MAUDE data base. For instance, the FDA did not exempt ASR participating manufacturers from reporting *within 5 days* device associated events related to deaths and when action is necessary to prevent substantial harm to public health.[14] A device manufacturer was required to report all serious events to FDA's MAUDE data base which is available to the public, even when the manufacturer participated in the ASR program.

51. As of 2019, the ASR program is no longer available to device manufacturers due to its misuse [15].

52. Defendants (and each of them) breached their reporting duties by using the ASR program to keep the scope and seriousness of injuries related to surgical staplers hidden from surgeons and the public and kept important and relevant safety information from the Plaintiff and her caregivers.

53. Plaintiff's injuries occurred during this timeframe of "hidden harms." Since the discovery of this conduct by Defendants, the staplers substantially equivalent to the stapler used on Plaintiff have been the subject of a recall.

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[13] 21 CFR 803.50 Subpart E reads in part: Manufacturer Reporting Requirements: a) if you are a manufacturer, you must report to us [FDA] . . .no later than 30 calendar days after the day that you receive or otherwise become award of information, from any source, that reasonably suggests that a device that you market:

1) May have caused or contributed to a death or serious injury or, 2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

[14] Types of Events not covered by [ASR] exemption: a) Events that require the submission of a 5-day report, b) Events where the device, . . ., may have caused or contributed to death. (Guidance for Industry Medical Device Reporting-Alternative Summary Reporting (ASR) Program.) 2000, October 19.

[15] *Statement on agency's efforts to increase transparency in medical device reporting*. https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-increase-transparency-medical-device-reporting

54. In October 2021, the FDA reclassified Surgical Stapler devices from Class 1 devices (as used for Band-Aids and cotton balls) to Class 2 devices, which will now make devices, such as the device used on Plaintiff, subject to premarket review.

55. The consequences of a malfunction are profoundly serious, as the FDA has explained, "[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence."[16]

56. Injuries caused by malfunctioning internal surgical staplers can be permanent and fatal.

57. Even if the malfunction does not cause a potentially fatal injury for the patient, such "complications frequently require additional diagnostic studies, invasive procedures and in the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care."[17]

58. As a result of these complications and the ubiquitous malfunctions that have plagued surgical staplers for years, the FDA conducted a review of the studies that have been conducted to investigate these issues.[18]

59. By examining these studies, the FDA concluded that the most commonly reported malfunctions associated with surgical stapler systems include malformed staples, missing staples, *staplerjamming, and misfires*. [*Emp. Added*][19]

60. Overall, Defendants at all relevant times were, or should have been, aware of the dangers a defective surgical stapler system posed for the general public and should have, as required by the FDA's regulations governing medical device manufacturers, to maintain effective procedures to properly manufacture the surgical stapler system and appropriately respond whenthe stapler was found to be defective. Unfortunately, this is not the case.

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[16] *FDA Executive Summary, FDA (May 30, 2019),* at 11. download (fda.gov).
[17] *Id.* at 9.
[18] *Id.* at 10.
[19] *Id.* at 10-11.

61. The surgical staplers at issue in this action were designed, tested, manufactured, monitored, and marketed by Defendants, and malfunctioned during Plaintiff's surgery. That malfunction caused Plaintiff to undergo subsequent hospital stays, extensive medical treatment and suffer economic harm.

62. Had the Plaintiff been truthfully informed of the risks associated with the Surgical Stapler system used during her surgical procedure, she, and her physician would not have used the device during her surgery.

Manufacturer-Created Knowledge Gap

63. In many operations, surgical staplers are used to ligate and divide major blood vessels and other structures. The device cuts the tissue, and then it staples the open tissue closed. This frequently occurs in laparoscopic procedures, which are greatly facilitated by using surgical staplers and are associated with lower risk of surgical site infection. This less invasive form of surgery does not require large incisions, and surgical staplers allow surgeons to perform procedures within laparoscopic operations that carry a high risk of infection, such as anastomoses, more rapidly.[20] However, there is no pause and no indicator of stapler success before the cutting blade activates.[21] Additionally, adequate grip strength is necessary to fire the stapler, yet too much force too quickly can put pressure on delicate tissue and damage it.[22] The device's complexity is perhaps best illustrated by the complicated process of choosing the right stapler and corresponding staple cartridge for the specific type of tissue involved in a procedure. The selection of a stapler based on shaft length, lumen size, and stapler height can have a great effect on the clinical outcome.

[20] Y. Kagawa, *The association between the increased performance of laparoscopic colon surgery and a reduced risk of surgical site infection*. 49 Surg Today 474 (Jan. 2019).
[21] Helen J. A. Fuller, *Surgical Stapler Adverse Events in the Veterans Health Administration: Root Causes and Lessons Learned*, 3 Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care 1, 153 (July 2014)
[22] *Id.*

Staple height, in particular, is a key decision as choosing a staple height that is incompatible with a specific tissue's thickness and biomechanical properties can lead to improper staple formation, resulting in anastomotic leaks, tissue damage, and other complications. A variety of model types and functionality provide customized tool selection, but the same choices make consistent safe use difficult.[23] Despite the importance of this selection, very little guidance is provided by Defendants, and staple selection and operation is therefore largely based on anecdotal evidence and the practices of attending surgeons passed down from teacher to student at each institution.[24]

64. Doctors and surgeons appropriately depend upon the manufacturers to educate them on their products, and manufacturers are required to properly instruct physicians on the safe use of their product, which Covidien fails to do adequately. Since surgical staplers are constantly evolving and being created for an ever-increasing list of procedures, without sufficient training, instruction, and education. Defendants have created a 'knowledge gap' in the medical community concerning safe use of the product.

65. For example, in a cohort study of 210 laparoscopic general surgery cases over a two-year period, medical device-related interruptions during procedures occurred frequently and were classified into five distinct categories, of which device failure was the most common. Laparoscopic staplers contributed to over 50% of these device failures and 25% of all interruptions of any category.[25] The authors attribute the pervasiveness of surgical stapler failure in their research to the "accelerated innovation and development [of surgical staplers] and **lack of systematic data collection after the implementation of surgical devices**."[26] [*emphasis added*]

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[23] Fuller, *supra.*
[24] Edward Chekan, *Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes*, 7 Med Devices Auckl. 305 (Sept. 2014).
[25] James J. Jung, *Characterization of device-related interruptions in minimally invasive surgery: need for intraoperative data and effective mitigation strategies*, 33 Surg Endosc. 3, 717 (March 2019)
[26] *Id.*

66. In fact, one survey found that the incidence rate of surgical stapler malfunction is so high that "86% of laparoscopic surgeons either had personal experience with or knew of surgeons who experienced stapler malfunction."[27] Other studies have found that, on average, 8,000-9,000 AEs related to surgical staplers occur per year, with 90% of these AEs resulting from a malfunction with the device.[28]

67. The Defendants knew, or should have known, about this knowledge gap discussed at length in a 2014 medical literature review published by doctors with industry ties. The review cites a previous study which identified a wide educational gap in surgical stapling and posits that in order to bridge the educational gap, the surgical stapler manufacturing industry must work together with the medical community:

> McColl et al created a multiple-choice test to assess general surgery residents' knowledge on the purpose and function of linear, circular, and laparoscopic staplers. The test was administered both before and after a 40-minute didactic teaching lecture delivered through a collaborative effort between an attending general surgeon and industry representative with comprehensive knowledge of stapling devices. Mean test scores significantly increased from 53% (pretest) to 77% (posttest), ($P<0.05$). In this small group ($n=26$), this study again identifies a significant gap in existing stapling knowledge and showed the feasibility and value of industry–surgeon collaboration to develop an effective educational program for clinicians.[29]

The authors later double down on their conclusions regarding education needed to avoid patient injury by ensuring surgeons are adequately informed on the safe use of the device, stating that:

> Bringing the surgical community together with other professionals in the device industry, such as stapler manufacturers, engineers, and scientists, to collaborate on the development of educational programs to keep surgeons apprised of the optimal use of medical devices should be a national priority. To facilitate this process, *currently available data* need to be *collected in a principal location* and critically assessed and summarized. Further, prospective databases into which surgeons can *enter specific case information* regarding their stapling practices (*type of stapler*, staple size, tissue thickness, etc.) and short-term clinical results (leak, bleeding, stricture, and diversion rates) need to be developed.

[27] Samwel Okoth Makanyengo and Dhan Thiruchelvam, *Literature Review on the Incidence of Primary Stapler Malfunction,* 27 SURG. INNOV., 229-34 (Apr. 2020)
[28] *Everything Healthcare Professionals Need to Know, supra* note 15.
[29] Chekan, *supra*.

> Purposefully and carefully studying current stapling methods will, hopefully, lead to the development of more specific and scientifically based recommendations regarding the choice of staple height and best stapling methods for the diverse range of clinical situations encountered by surgeons. (Emphasis added)[30]

68. The FDA recognized this need to gather data on specific surgical devices and the negative clinical cases associated with them. Since the 1990s, the FDA has given manufacturers, the medical community, and the public at large access to the MAUDE Database (the Manufacturer and User Facility Device Experience Database) for all surgical and medical devices. A 2017 journal article describes MAUDE in the following manner:

> MAUDE contains over four million medical device adverse event and product problem reports dating back to 1991. With nearly two thousand new adverse event and product problem reports submitted every day the MAUDE database is an important tool for monitoring and investigating safety issues involving medical devices. MAUDE has facilitated the identification and investigation of medical product problems ranging from cardiovascular and gynecological devices to stretchers and tanning beds.[31]

Regarding its utility to the medical community and ability to search for specific products, the authors state:

> The FDA uses MAUDE reports to monitor device performance, detect potential device-related safety issues, and inform the risk-benefit assessments of these products. Health care professionals use MAUDE to review events associated with specific products, body systems or procedures. More than 120 articles referencing MAUDE have been published to date, the majority of these summarizing adverse events specific to a particular outcome, product or body system.[32]

69. For surgeons who use a variety of surgical devices daily, MAUDE allows them to familiarize themselves with new technologies and identify and analyze trends in malfunctions. Over the 20-year period in which the ASR reporting system remained an industry secret, "[d]ata from MAUDE also established what was assumed to be the baseline incidence and prevalence of

[30] *Id.*
[31] Lisa Garnsey Ensign, *A Primer to the Structure, Content and Linkage of the FDA's Manufacturer and User Facility Device Experience (MAUDE) Files*, 5 EGEMS Wash DC 1, 12 (June 2017).
[32] *Id.*

surgical device malfunctions and related patient harm or death. Other studies used this data to assess the safety and efficacy of staplers for procedures in the specialties of colorectal, pancreatic, bariatric, and robotic surgery."[33]

70. As one of the largest surgical stapler manufacturers in the world, Covidien has been in possession of massive amounts of data on surgical stapler-related injuries, fatalities, and malfunctions. But rather than contributing this knowledge to the powerful MAUDE database, Defendants purposely kept this information from the attention and scrutiny of the public. As will be discussed in depth below, in the almost seven years preceding Kimberly Bell's bariatric procedure, the medical providers who performed her surgery were deprived of over half of Covidien's data on adverse events associated with its staplers, totaling over 56,000 reports that were never publicly submitted.

Alternative Summary Reporting

71. It was just subsequent to this era of clandestine reporting that Kimberly Bell's initial surgery (September 11, 2019) occurred, a context which is critical to understanding how a defective surgical stapler ended up in the hands of her surgeon, Dr. Ng Ahmed. Per the FDA's Executive Summary issued in May 2019:

> Prior to February 2019, surgical staplers for internal use were also eligible for the ASR Program. This 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. FDA carefully reviewed and considered all such reports but reports prior to 2017 were not made publicly available because the format was not compatible with the public database. [34]

72. The existence and subsequent corrupted use of the aforementioned Alternative Summary Reporting (ASR) Program was publicly revealed in a March 2019 article by Christina Jewett of

[33] Samwel Okoth Makanyengo, *Literature Review on the Incidence of Primary Stapler Malfunction*, 27 Surgical Innovation 2, 229 (Dec. 2019).
[34] *FDA Executive Summary*, *supra, at 12*.

Kaiser Health News (KHN). The investigative piece featured insights from various ex-FDA officials who worked for the agency at the inception and throughout the lifespan of the ASR program, including Larry Kessler. The origins of the ASR program, which was in place from 1997 until it was formally ended in June 2019, are described in the following manner:

> The alternative summary reporting program started two decades ago with a simple goal: to cut down on redundant paperwork, according to officials who were at the FDA at the time.
>
> Kessler, the former FDA official, said the program took shape after scandals over under-reporting of device problems spurred changes allowing criminal penalties against device companies.
>
> Soon, thousands of injury and malfunction reports poured into the agency each month, with about 15 staff members dedicated to reviewing them, Kessler said. Many reports were so similar that reviewing them individually was "mind-numbing." Kessler went to the FDA's legal department and to device manufacturers to propose a solution.
>
> Device makers would be able to seek a special "exemption" to avoid reporting certain complications to the public database. The manufacturers would instead send the FDA a spreadsheet of injury or malfunctions each quarter, half-year, or year.
>
> That way, Kessler said, reviewers could quickly look for new problems or spikes in known issues. When the program launched in 2000, the list of exempted devices was made public and only a few devices were involved, Kessler said.

In 2019, for reasons as yet unknown, the list of exempted products was no longer public. "I don't know why it's not [made public] now," Kessler said. "I'm surprised about that."[35]

73. The series of articles by KHN, in combination with its many FOIA requests, eventually spurred the FDA to release all of its previously undisclosed ASR data.[36] Comparing this secret data with the data that had been publicly available revealed some shocking statistics from the years preceding Kimberly Bell's surgery. Malfunctions associated with EGIA45AVM, EGIA60AVM, and the EGIAUXL handle to which the reloads were affixed during the surgery were in fact entered

[35] Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, KAISER HEALTH NEWS, https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/, (March 7, 2019).
[36] *MDR Data Files*, FDA.GOV, https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files, (content current as of February 18, 2022).

into the secret system. The data on Defendants' total usage of the ASR system is summarized by the bullet points below:

- In 2011, Covidien submitted over 4,800 adverse event reports related to surgical staplers to the ASR program. Of those reports, 154 were specifically related to the EGIAUXL surgical stapler handle; 118 were specifically related to the EGIA45AVM; and 132 were specifically related to the EGIA60AVM.
- In 2012, Covidien submitted over 6,800 adverse event reports related to surgical staplers to the ASR program. Of those reports, 149 were specifically related to the EGIAUXL surgical stapler handle; 284 were specifically related to the EGIA45AVM; and 258 were specifically related to the EGIA60AVM.
- In 2013, Covidien submitted over 6,400 adverse event reports related to surgical staplers to the ASR program. Of those reports, 235 were specifically related to the EGIAUXL surgical stapler handle; 274 were specifically related to the EGIA45AVM; and 292 were specifically related to the EGIA60AVM.
- In 2014, Covidien submitted over 14,000 adverse event reports related to surgical staplers to the ASR program. Of those reports, 835 were specifically related to the EGIAUXL surgical stapler handle; 486 were specifically related to the EGIA45AVM; and 500 were specifically related to the EGIA60AVM.
- In 2015, Covidien submitted over 8,900 adverse event reports related to surgical staplers to the ASR program. Of those reports, 596 were specifically related to the EGIAUXL surgical stapler handle; 288 were specifically related to the EGIA45AVM; and 242 were specifically related to the EGIA60AVM.
- In 2016, Covidien submitted over 9,900 adverse event reports related to surgical staplers to the ASR program. Of those reports, 659 were specifically related to the EGIAUXL surgical stapler handle; 342 were specifically related to the EGIA45AVM; and 326 were specifically related to the EGIA60AVM.
- In 2017, Covidien submitted over 4,700 adverse event reports related to surgical staplers to the ASR program. Of those reports, 355 were specifically related to the EGIAUXL surgical stapler handle; 134 were specifically related to the EGIA45AVM; and 153 were specifically related to the EGIA60AVM.

74. Comparing the ASR-reported figures to the MAUDE numbers shows the scope of potential life-saving knowledge that was hidden from medical providers. This is illustrated by the table and bullet points below:

Year	2011	2012	2013	2014	2015	2016	2017	2018
Covidien Surgical Stapling Entries in ASR Program*	4,800	6,800	6,400	14,000	8,900	9,900	4,700	-
Covidien Surgical Stapling Entries in MAUDE	0	747	894	1,316	1,111	1,693	5,037	~11,000
Covidien EGIAUXL Entries in ASR Program	154	149	235	835	596	659	355	-
Covidien EGIAUXL Entries in MAUDE	0	3	0	7	10	64	444	636
Covidien EGIA45AVM Entries in ASR Program	118	284	274	486	596	659	134	0
Covidien EGIA45AVM Entries in MAUDE	0	3	0	3	13	30	109	263
Covidien EGIA60AVM Entries in ASR Program	132	258	292	500	242	326	153	0
Covidien EGIA60AVM Entries in MAUDE	0	0	0	2	16	35	147	191

*Numbers have been rounded to nearest ten or hundred

- From January 1, 2011, through December 31, 2018, the FDA received almost 110,000 reports related to issues with surgical staplers[37].
- Over half of these reports–56,277 in total–were submitted secretly through the ASR program[38].
- Going back further to 2001, this number increases to more than 66,000.

[37] FDA Executive Summary, *supra* at p. 13
[38] *Id.*

The Effects of ASR Program Abuse

75. While the FDA's reason for using this program may have been a pragmatic one, manufacturers like Covidien Medtronic chose to over-report via ASR and under-report via MAUDE for one clear motive: profit. The secrecy of the ASR program was advantageous to sales representatives and company executives alike, shielding them from public scrutiny and allowing them to provide potential buyers with only the publicly reported adverse event reports associated with their products. The ability to hide malfunctions and injuries associated with Covidien products undoubtedly increased their merchantability. To put it in perspective, a Covidien sales representative promoting an EGIAUXL surgical stapler handle in 2017, just two years before Kimberly Bell's procedure with that stapler, would be able to omit approximately 45% of the total number of adverse events reported for that year when making a sales pitch. That same sales representative promoting either the EGIA45AVM or EGIA60AVM surgical stapler in 2017, again just two years prior to Ms. Bell's procedure with these staplers, would be able to omit approximately 55% and 51%, respectively, of the total number of adverse events reported for that year when making a sales pitch.

76. If looking to promote the safety and reliability of Covidien's surgical stapling system as whole, that same salesperson could hide roughly 50% of the total number of adverse events, only being obligated to disclose just about 5,000 out of the roughly 10,000 reported malfunctions and injuries

77. The stark contrast in reporting only becomes more apparent heading back toward 2012, with 2014 being a particular egregious year (to be discussed below). These earlier numbers are highly relevant and concerning nonetheless, especially given that surgical stapling products have

a long shelf-life and can often take five years to be considered 'expired' once purchased by a medical facility.

78. The sheer magnitude of surgical stapling system-related reports that were submitted via ASR clearly suggests a level of risk that was unknown to researchers, physicians, and the public alike. Despite this, data analysis suggests that the longer this secretive reporting system went undetected, the more emboldened Covidien became. From 1999 to 2018, Covidien surgical stapler reports to ASR increased yearly versus MAUDE, with a positive correlation between number of reports to ASR and calendar year. In contrast, the MAUDE database showed negative trends over the calendar years for surgical staplers, with the rate of reporting on surgical staplers decreasing annually by 24%. In total, 84.4% of all surgical stapler malfunctions were reported via ASR, with a peak of 97.9% of all surgical stapler malfunctions being secretly reported in 2014.[39] Covidien reaped great benefits from that year of excessive secret reporting, as it was acquired by Medtronic in 2015. According to Medtronic's fourth quarter and fiscal year 2015 financial results, the company's Surgical Solutions branch, which includes surgical staplers, posted a revenue of $1.293 billion and cited staplers as major drivers of revenue performance.[40]

79. While Covidien enjoyed increasing economic benefits from the ASR program as time went on, the medical community was denied critical information that could have informed their decisions to select one Covidien stapler over another or to purchase any Covidien stapling products at all. By keeping the scope of injuries related to surgical staplers hidden, surgeons only had access to the diluted public reports, which meant that injuries, malfunctions, and trends did not seem as

[39] Derek A. Benham, *Revealing the scope of surgical device malfunctions: Analysis of the "hidden" Food and Drug Administration device database*, 221 AM. J. SURG. 6, 1121 (June 2021).
[40] *Medtronic Reports Fourth Quarter and Fiscal Year 2015 Financial Results*, GLOBE NEWS WIRE, https://www.globenewswire.com/news-release/2015/06/02/1891811/0/en/Medtronic-Reports-Fourth-Quarter-and-Fiscal-Year-2015-Financial-Results.html, (June 2, 2015).

prevalent. Some of this essentially non-reporting also involved new and novel malfunctions that caused severe injury and would have subjected their staplers to recall or reclassification.

80. Perhaps most importantly, the lack of public information and post-market reporting from Covidien adversely affected the knowledge and decision making of experts like the surgeon who performed Kimberly Bell's procedure, creating a dangerous landscape in which to be operating and preventing the surgeons from making informed decisions. Covidien's conduct directly led to Kimberly Bell's physician electing to use a surgical stapler without full knowledge of all foreseeable risks.

Device Regulations and Recall

81. Under 21 CFR 820, *et seq.,* medical device manufacturers, like Defendants, must establish and follow Quality Systems ("QS") that ensure their products are manufactured according to specifications, once manufactured performs as intended for use, and can safely be used in patient surgical procedures. QS for FDA-regulated products, including medical devices, are known as Current Good Manufacturing Practices ("CGMP's").[41]

82. As opposed to other medical devices, surgical staplers were considered a Class I medical device, and Defendants were not required to obtain FDA's approval on their manufacturing processes, establish safety and efficacy profiles, nor Premarket Approval (PMA) before selling a surgical stapler.[42]

83. Thus, utility and safety profiles, and the safety of surgical staplers were never reviewed nor approved by the FDA.

84. Further, the FDA never reviewed nor approved manufacturing processes for any lines of the internal Surgical Stapler.

[41] *See* 21 CFR 820.
[42] *FDA Executive Summary, FDA (May 30, 2019)* download (fda.gov).

85. Finally, as a Class I medical device which does not require premarket approval from the FDA also means Defendants' surgical stapler lines did not require device design controls as Class II devices do.[43]

86. However, as surgical staplers for internal use are often submitted bundled together with staples in 510(k) submissions for Class 2 implantable staples, the FDA has cleared various indication for use (IFU) statements for surgical staplers and staples through the 510(k) process for implantable staples.[44]

87. As a consequence, Defendants were given unfettered freedom to design, manufacture and market surgical staplers.

88. However, Defendants were not permitted to ignore FDA imposed regulations under its Medical Device Reporting requirements, nor its requirements to establish an effective QS and CGMP's under 21 CFR 820, *et seq*.

89. Despite this and the potential for serious injury, Defendants failed to maintain QS and CGMP's to ensure that its surgical staplers such as the stapler used in Plaintiff's procedure, would not feature any manufacturing defects, and expose patients to risks of serious injury or death when the device is used as intended by the surgeon.

90. Further, abuse in the utilization of the ASR system resulted in Defendants' marketing and selling a device which posed grave dangers to an unknowing medical and patient community.

91. However, corporate Defendants knew, and/or had reason to know, because of the thousands of adverse events that the company received or had reason to know, that surgical staplers, such as the device used during Plaintiff's surgical procedure, were defective, unreasonably dangerous, and not safe.

[43] Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers | FDA (March 8, 2019)
[44] *FDA Executive Summary, FDA (May 30, 2019),* at 7.

92. Defendants' failure to establish *effective* CGMP's, "AE" complaint reporting, and investigation units, allowed a serious manufacturing defect to go unreported after defective staplers were released to the U.S. public.

FDA Response to Covidien Recall and Surgical Stapler Malfunctions

93. On March 8, 2019, the FDA issued a letter to healthcare providers highlighting the problems related to surgical staplers.[45]

94. By April of 2019, the FDA announced its intent to reclassify surgical staplers from a Class I device (signifying low risk of harm to patients) to a Class II device, requiring a stricter approval process.[46]

95. The FDA explained that it intended to "to reclassify surgical staplers for internal use from Class I (general controls), exempt from premarket review to Class II (special controls), subject to premarket review. The FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance."[47]

96. The FDA reasoned that this reclassification was necessary, in part, due to complications that can result from surgical stapler malfunctions, which could result in "prolonged surgical procedures, unplanned surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death."[48]

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[45] *Surgical Staplers and Staples for Internal Use – Labeling Recommendations,* FDA (April 2019) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations.

[46] *General and Plastic Surgery Devices: Reclassification of Certain Surgical Staplers,* FED. REGISTER (Apr. 24, 2019). https://www.federalregister.gov/documents/2019/04/24/2019-8260/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers

[47] *Id.*

[48] *Id.*

97. The FDA also noted and illustrated the high rate of reported incidents, also known as Medical Device Reports ("MDRs"), associated with surgical staplers. The FDA summarized its findings by explaining that:

> From January 1, 2011, to March 31, 2018, FDA received over 41,000 individual MDRs for surgical staplers and staples for internal use, including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. Some of the most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to tissue).[49]

98. It was also noted that "[t]he most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty of opening/closing the stapler, stapler misfiring, and stapler breakage. The most commonly reported patient consequences from malfunctions with surgical staplers for internal use included a delay in surgical procedure, hemorrhage, and tissue damage."[50]

99. Beyond these findings, however, the FDA also reported that "[f]rom November 1, 2002, to December 30, 2018, the FDA received a total of 168 recalls for surgical staplers and staples for internal use under product codes GAG and GDW, including one class I recall and 167 class II recalls.[51]

100. As a result of the aforementioned data and findings, on or around April 24, 2019, the FDA issued a proposed order to allow for this reclassification. This proposed reclassification would include, among other requirements, adequate performance testing to mitigate the risk of device malfunction and would "include an evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type; measurement of the worst-case deployment

[49] *Id.*
[50] *Id.*
[51] *Id.*

pressures on stapler firing force; and a measurement of staple line strength."[52]

101. That same day, the FDA also issued a draft guidance document to assist with the labeling of surgical staplers.[53] The FDA explained that "[b]oth device misuse and device malfunctions are root causes of these adverse events. FDA believes that these problems may be mitigated by providing specific information about the risks, limitations, and directions for use in the labeling for the surgical staplers and staples for internal use."[54]

102. Because of the risks associated with surgical staples, and to allow public comment, the FDA held a public meeting on or around May 30-31, 2019, to discuss whether surgical staplers should be reclassified as a Class II medical device, which would require manufacturers to give "premarket notification and allow the FDA to establish mandatory special controls to help mitigate known risks of the device."[55]

103. At the conclusion of the meeting, the FDA panel "unanimously recommended the reclassification of surgical staplers for internal use from Class I (general controls) to Class II (special controls).[56] A final order was issued on the reclassification and became effective October 8, 2021, wherein surgical staplers for internal use would be classified as a Class II (special controls) device and subject to premarket review[57].

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[52] *Id.*

[53] *Surgical Staplers and Staples for Internal Use-Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff: Availability,* FED REGISTER (Apr. 24, 2019), http://www.federalregister.gov/documents/2019/04/24/2019-08259/surgical-staplers-and-staples-for-internal-use-labeling-recommendations-draft-guidance-for-industry.

[54] *Id.*

[55] *General and Plastic Surgery Devices Advisory Committee Meeting,* FDA (May 30, 2019), https://www.fda.gov/media/127627/download.

[56] *Id.*

[57] Federal Register: General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers

Recalls and Defective Product Lines: EGIAUXL Handle

104. In addition to operating while uninformed, Kimberly Bell's providers were saddled with equipment that was both actively under recall and part of a problematic product line. As previously stated, the surgical stapling products used in this case were a combination of the EGIAUXL handle and two different reloads with Tri-Staple Technology, the EGIA45AVM and the EGIA60AVM. On February 18, 2016, the FDA announced a Class II recall of the EGIAUXL Endo GIA Ultra Universal XL, affecting over 325,000 units world and nationwide. Defendants stated the reason for the recall was that "staplers fail to fire or partially fire" and that there were "reports of the instrument articulating level disengaging during use." The recall was terminated July 18, 2019, meaning that just two months prior to the time of Plaintiff's surgery, the stapler handle was still under active recall.

105. Given the September 2019 date of Plaintiff's ill-fated procedure, her surgical team still faced the full-fledged hazard of a stapler handle known to malfunction by failing to fire or partially firing staples, a defect which could certainly cause an anastomotic leak at the staple line like the injury suffered by Plaintiff.

Recalls and Defective Product Lines: EGIA45AVM and EGIA60AVM Reloads

106. The two reloads which Ms. Bell's surgeon attached to the defective handle was part of Defendants' trademark line of Endo GIA Reloads with Tri-Staple Technology (see Figure 3).

Figure 3

Endo GIA™ Reloads with Tri-Staple™ Technology

MEDTRONIC

Standard Reload Length	Device	Reorder Code	Color Code	Staple Heights	Tissue Type
30 mm		SIG30AV¹	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG30AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG30AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
45 mm		EGIA45AV¹	Gray	2 mm, 2 mm, 2 mm	Vascular
		EGIA45AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		EGIA45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA45AMT	Purple	4 mm, 4.5 mm, 5.0 mm	Medium/Thick
		EGIA45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIG45AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
60 mm		—	—	—	—
		EGIA60AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIG60AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
Reinforced Reload Length	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
45 mm		SIGTRSB45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGTRSB45AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
60 mm		SIGTRSB60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGTRSB60AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
Signia™ Small Diameter Reload	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
30 mm		SIGSDS30CTV	Gray	2 mm, 2 mm	Vascular
		SIGSDS30CTVT	White	2.5 mm, 2.5 mm	Vascular/Medium
45 mm		SIGSDL45CTVT	White	2.5 mm, 2.5 mm	Vascular/Medium
Curved Tip Reload Length	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
30 mm		SIG30CTAV¹	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG30CTAVM	Tan	2mm, 2.5mm, 3 mm	Vascular/Medium
45 mm		SIG45CTAV¹	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG45CTAVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG45CTAMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
60 mm		SIG60CTAVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG60CTAMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
Radial Reload	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
		SIGRADMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGRADXT	Black	4 mm, 4.5 mm, 5 mm	Extra Thick

107. This Tri-Staple product line of roughly 30 reloads consists of Standard, Reinforced, Small Diameter, Curved Tip, and Radial reloads, with Plaintiff's reloads falling into the Reinforced category. All of these categories of reloads are essentially variations of the same design and are manufactured to be compatible with the EGIAUXL handle. They are substantially similar in size,

material, composition, design, and intended use. The mechanisms for attaching, detaching, and firing are also the same.

108. It should come as no surprise then that when a manufacturing problem plagues one Tri-Staple reload, it plagues them all. From 2018 up until most recently in 2021, more than 20 products within the Tri-Staple reload product line have been recalled, which can be broken down by Defendants' reasons for the recalls in the following manner:

- Device missing sled component (May 2018 – 3 Tri-Staple reload varieties recalled)
- Device missing sled component (July 2018 – 14 Tri-Staple reloads recalled)
- Device may be missing a pin component (June 2019 – 5 Tri-Staple reload varieties recalled)
- May contain an extra laminate layer (April 2021 – 1 Tri-Staple reload variety recalled)

109. By the time Plaintiff's surgery involving two different varieties of Tri-Staple reloads had taken place in September 2019, there had already been 22 instances of Tri-Staple reloads being recalled for defects, almost all of which were explicitly said by the FDA to potentially cause anastomotic leaks. Given the substantial technical similarity between all the iterations of the Tri-Staple reload product line, it is more likely than not that the design processes, manufacturing processes, and quality control measures associated with these staplers are also shared. The surgery that caused Kimberly Bell's injuries took place in the context of a veritable whirlwind of Tri-Staple reload recalls, and her particular injury, anastomotic leak, was a known consequence of these defects.

Defective Product Family

110. The recently under-recall EGIAUXL stapler handle and the entire product family of compatible Tri-Staple reloads, and more specifically the EGIA45AVM and EGIA60AVM variations that are at issue in this action (which are still under an active recall), were designed, manufactured, and marketed by Defendants, and malfunctioned during Kimberly Bell's surgery.

That malfunction caused her to undergo further surgical procedures and prolonged medical treatment. As a direct and proximate result of the actions and/or omissions by the Defendants, Kimberly Bell suffered serious and permanent injuries and damages, including but not limited to:

a) Acute Respiratory Failure;
b) Pulmonary edema leading to septic shock secondary to anastomotic leak;
c) Acute Kidney injury requiring dialysis;
d) Mechanical Ventilation;
e) Atrial Fibrillation;
f) Drain Placement;
g) Wound Debridement;
h) Wound Vac;
i) Persistent Leak;
j) Multiple surgeries/procedures;
k) Ongoing medical treatment;
l) Lost chance of recovery or survival;
m) Pain, suffering, mental anguish, fear, loss of enjoyment of life and emotional distress;
n) Medical expenses.

GENERAL FACTUAL ALLEGATIONS

111. Plaintiff contends that Defendants designed, tested, manufactured, marketed, sold, and monitored, a defective class of surgical stapler systems that includes the Endo GIA, and other related products.

112. Defendants design, test, manufacture, market, sell, and monitor the Endo GIA Surgical Staplers, surgical staplers to be used by medical service providers in surgical procedures. The staplers come in various models, to assist surgeons in creating a secure anastomosis within the body and form a seal.

113. Defendants designed, tested, manufactured, marketed, sold, and monitored a defective product family of Endo GIA Surgical Staplers which were available in the market to be used in surgical procedures before, during, and after the time of Ms. Bell's surgery. These staplers frequently malfunctioned and were defective, compromising staple integrity and surgical

procedures, with the potential to lead to patients' death or serious injuries when used by a surgeon, even as instructed by Defendants in the device user manual.

114. That at all times relevant to this matter, Defendants were aware its device would malfunction in the manner suffered by Plaintiff Kimberly Bell and failed to inform the medical community or the public that its surgical stapler device system was defective and would harm patients when it failed to perform in the manner it for which it was designed.

115. By 2013, Defendants and the medical device industry were aware that malfunctioning surgical staplers presented serious risks of injuries during surgery and that the true risk of injury was unknown and unexamined. Despite this obvious problem, these Defendants took no steps to measure the true risks of these devices.

116. These staplers frequently malfunctioned and were defective, compromising staple integrity and surgical procedures, with the potential to lead to patient death or serious injuries when used by a surgeon, even as instructed by Defendants in the device user manual.

117. Plaintiff contends that a surgical stapler tested, designed, manufactured, marketed, sold, and monitored by Defendants, malfunctioned during Plaintiff Bell's September 2019 surgery, resulting in an internal staple line failure that caused anastomotic leak which required additional corrective surgeries, sepsis, and a shockingly prolonged hospital stay. The leak sufficiently damaged tissue, causing delay in healing that continues to this day.

118. Plaintiff alleges, upon information and belief, that the Endo GIA stapler handle and reloads used in Kimberly Bell's surgery to create her staple line was defective, causing the staple line leak. This stapler was a model in a class of staplers known by Defendants to malfunction or to contain defects, whether it was included specifically in a recall or not.

119. Defendants intentionally failed to: (1) provide warnings regarding the potential for their

staplers to malfunction in the very manner that occurred during Plaintiff's surgery; (2) warn and inform surgeons of the potential for its staplers to malfunction in that manner, including all foreseeable use and misuse of the product; (3) train, instruct, and educate surgeons regarding safe use and foreseeable misuse of their product; and (4) recall their defective products when Defendants knew their surgical staplers were prone to injurious malfunction, and to timely and properly effectuate the recall. Through that conduct – as well as the affirmative concealment of the known risks of the products 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.

120. That conduct was motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement, and cost avoidance, to the virtual exclusion of all other considerations.

121. Such egregious conduct was the direct cause of physical, emotional, and economic harm to Plaintiff, Kimberly Bell.

COUNT I:

BREACH OF WARRANTY – DEFECTIVE MANUFACTURE AND DESIGN

122. Plaintiff hereby incorporates by reference the preceding paragraphs as if fully set forth herein.

123. Defendants impliedly warranted that the Endo GIA 45mm with Tri Staple Technology (EGIA45AVM), and/or the Covidien Endo GIA 60mm with Tri Staple Technology (EGIA60AVM), and/or the Covidien Endo GIA Universal XL (EGIAUXL) were merchantable and were fit for the ordinary purposes for which they were intended.

124. When Plaintiff's surgeon performed a Laparoscopic Biliopancreatic Diversion with Duodenal Switch, 100 cm common channel and 100 cm roux limb, TAPP block, and Laparoscopic

Hiatal Hernia Repair, the stapler device and reloads were being used for the ordinary purposes for which they were intended.

125. Plaintiff Kimberly Bell, individually and/or by and through her surgeon, relied upon the Defendants' implied warranties of merchantability in consenting to have the procedure with heavy usage of permanently implanted surgical staples.

126. Defendants breached these implied warranties of merchantability because the stapler used to form the staple line were neither merchantable nor suited for their intended uses as warranted.

127. Defendants' breach of its implied warranties resulted in the implantation of a faulty staple line which later burst, spewing biliary contents into Plaintiff's lower abdomen, requiring multiple surgeries and an extended hospitalization.

128. The defective Endo GIA Surgical Stapler System used in Kimberly Bell's surgery resulted from an improper or incorrect manufacturing process, such that the devices as manufactured deviated from their intended design. The defects caused by improper or incorrect manufacturing rendered them unreasonably dangerous, deficient, and defective to Plaintiff. These defects existed since the devices were manufactured, meaning that the defects were present when the device system left the possession and control of Defendants.

129. The Endo GIA stapler system used in Plaintiff's surgery was defective, unfit, unsafe, inherently dangerous, and unreasonably dangerous for their intended and reasonably foreseeable uses. The system was in said condition when it entered the stream of commerce and used in Kimberly Bell. As a result, the stapler system did not meet or perform to the expectations of patients and health care providers, but rather were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

130. The Endo GIA stapler system used on Plaintiff was defective at the time of its sale or

distribution, as the foreseeable risks of harm posed by the products at issue could have been reduced or avoided by the adoption of a reasonable alternative design. The omission of that reasonable alternative design renders the products at issue not reasonably safe. Reasonable alternative designs were available, technologically feasible, and practical, and would have reduced or prevented harm to patients like Plaintiff.

131. Defendants intentionally and recklessly designed, tested, manufactured, marketed, labeled, sold, distributed, and monitored the Endo GIA stapler systems with wanton and willful disregard for the health of Kimberly Bell, and with malice, placing their economic interest above the health and safety of Plaintiff.

132. As used by Plaintiff's surgeon, the Endo GIA stapler system was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. While they were used in the manner for which they were intended, the system was in such a condition that was unreasonably dangerous to Plaintiff, given its propensity to malfunction while forming staple lines, provoking anastomotic leaks, which is exactly the injury in which their use resulted.

133. At no time did Kimberly Bell have reason to believe that the surgical stapler system was in a condition not suitable for its proper and intended use among patients. She was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the system. Furthermore, in no way could Plaintiff have known that Defendants had manufactured the devices in such a way as to increase the risk of harm or injury to the patient on which they were used.

134. As a direct and proximate result of Defendants' wrongful conduct, including the design, manufacture, marketing, and distribution of the Endo GIA surgical stapler system, Plaintiff has sustained serious injuries and damages, including but not limited to multiple surgeries, multiple

life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, emotional distress, and medical expenses.

COUNT II:

BREACH OF WARRANTY – FAILURE TO WARN

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

136. The Endo GIA Surgical Stapler system used on Plaintiff presented a danger to patients like Plaintiff. Defendants were aware of the dangers the products at issue presented and knew that the danger would be present when the product was used in its intended manner, as it was here. Those dangers, however, were not known or reasonably knowable to patients like Plaintiff.

137. At no time did Kimberly Bell have reason to believe that the Endo GIA surgical stapler system was dangerous or in a condition not suitable for its proper and intended use among patients. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the system. Furthermore, in no way could Plaintiff have known that Defendants had manufactured the device in such a way as to increase the risk of harm or injury to the patient on which they were used.

138. As used by Plaintiff's surgeon, the Endo GIA surgical stapler system was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. While it was used in the manner for which it was intended, the System was in such a condition that was unreasonably dangerous to her, given its propensity to malfunction while forming staple lines, provoking leaks, which is exactly the injury in which its use resulted.

139. Defendants failed to provide proper warnings or instructions to the products end users and patients like Plaintiff so users and patients may reasonably avoid any hidden dangers associated

with the products at issue and use them safely. Defendants withholding of the Endo GIA surgical stapling system's true failure rate is purely motivated by profit.

140. As a direct and proximate result of Defendants' wrongful conduct, including the design, manufacture, marketing, and distribution of the Endo GIA Surgical Stapler System, Plaintiff has sustained serious injuries and damages including, but not limited to, multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, emotional distress, and medical expenses.

COUNT III: NEGLIGENCE

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

142. Defendants negligently designed, tested, manufactured, marketed, sold, monitored, and labeled the Endo GIA surgical stapler system.

143. Defendants had a duty to individuals, including Kimberly Bell, to use reasonable care in designing, testing, manufacturing, marketing, selling, labeling, distributing, and monitoring the Endo GIA surgical stapler system. A Defendant who designs a medical device or instrument, such as a stapler system, who sells or otherwise distributes a defective device is subject to liability for harm to persons caused by a design defect.

144. A reasonably prudent manufacturer must design its products so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to harm when the product is put to its intended use or to any use that is unintended but is reasonably foreseeable.

145. A medical device is defective if at the time of sale, the device is designed in such a way that it poses harm and risk of injury when used by the intended consumer in the manner the manufacturer has directed and designed.

146. A reasonably prudent manufacturer of those products would also know that an internal stapler system that fails to form solid staple lines could cause serious injury because a burst staple line failure can cause an anastomotic leak, and the injured patient would require multiple hospitalizations, surgeries, and significant medical care to treat.

147. A reasonably prudent manufacturer would comply with regulations promulgated to ensure the safety of its product.

148. Plaintiff was harmed by a defective Endo GIA surgical stapler system that was designed, tested, distributed, manufactured, sold, and monitored by Defendants. This system contained a design defect that made the product unreasonably dangerous to patients. Specifically, there was a design and/or manufacturing defect that would result in a stapler failing to form secure staple lines, despite proper utilization by a surgeon.

149. That design defect in the stapler system existed when the product left the manufacturer's control.

150. As a direct and proximate result of Defendants' negligence, Plaintiff has sustained serious injuries and damages including, but not limited to, persistent leak, multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, and emotional distress, and medical expenses.

151. Had Defendants not been negligent as outlined above Plaintiff would not have suffered from, and would not continue to suffer with, these serious injuries.

COUNT IV: NEGLIGENT MISREPRESENTATION

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

153. Defendants have a duty to Plaintiff, and others like Plaintiff, to show material facts relating

to the safe use of its product.

154. Defendants have negligently misrepresented to Plaintiff the safety of their Endo GIA surgical stapler system by hiding adverse events in the ASR system.

155. By using the ASR system, Defendants have made false statements regarding the true failure rate of their Endo GIA surgical stapler system.

156. Defendants' false statement was purely motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement, and cost avoidance, without consideration of the harm that could be, and has been, caused by their products.

157. Plaintiff, and her surgeon, used the information given to them as their basis for choosing to use the Endo GIA surgical stapler system.

158. Had Defendants been truthful, Plaintiff would have not agreed to the use of the Endo GIA surgical stapler system.

159. Defendants were aware of the dangers of the Endo GIA surgical stapler system. Defendants knew the manufacturing issues (reason for recall) but did nothing to fix the problem. Instead, Defendants continued to market the Endo GIA surgical stapler system knowing the risks that would be imposed on Plaintiff.

160. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiff has sustained serious economic loss in medical expenses, specifically paying for a defective device.

COUNT V: DECEPTIVE TRADE PRACTICES

161. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Complaint as fully copied and set forth her in their entirety.

162. As alleged above, Defendants sold and marketed the Endo GIA surgical stapler with a defective and unreasonably dangerous design and with insufficient and improper warnings.

163. Defendants Covidien LP, Covidien Sales, LLC, and Covidien Holding, Inc., are corporations with their headquarters in the State of Massachusetts and are registered to do business in the state.

164. The Defendants are required to comply with the laws of the state, including its Consumer Protection Laws.

165. Defendants Covidien LP, Covidien Sales, LLC, Covidien Holding, Inc., and Medtronic, Inc., business of designing, testing, manufacturing, sales, marketing and monitoring surgical staplers and are subject to the rules established under the *Massachusetts Consumer Protection Act, M.G.L. c. 93A, §2.*

166. Defendants engaged conduct that was in clear violation of the Act by the improper market and sale of the Endo GIA surgical stapler. Further, Defendants misrepresented the Endo GIA surgical stapler system as safe and effective to Plaintiffs, while failing to disclose the true failure rate of the Endo GIA surgical stapler.

167. Defendants misrepresented the Endo GIA surgical stapler as safe and effective to Plaintiffs, while failing to disclose its manufacturing practices failed to establish an effective Quality Systems Control, and compliant Good Manufacturing Practices as required under 21 CFR 820, *et seq.*

168. Contrary to Defendants' representations, the Endo GIA surgical stapler was not safe or effective when used for its intended purposes.

169. On August 4, 2022, Plaintiffs, through their attorneys, sent Defendants a written demand for relief pursuant to M.G.L. c. 93A, §9. Plaintiffs' demand letter identified her as a potential claimant, reasonably described the unfair acts or practices committed by Defendants that caused her injuries and made a reasonable tender of settlement.

170. Defendants' Registered Agent received Plaintiffs' demand letter on August 8, 2022, and

Defendants responded to Plaintiff's demand letter on September 7, 2022, and did not tender an offer.

171. Plaintiff suffered the aforementioned injuries and damages as a direct result of Defendants' violation of the Massachusetts Consumer Protection Act and Plaintiffs are entitled to any and all damages and recovery authorized pursuant to the Massachusetts consumer Protection Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Kimberly Bell prays for judgment against Defendants, individually and collectively, jointly, and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory damages allowable to Plaintiff;

(c) Judgment against Defendants for all other relief sought by Plaintiff under this complaint;

(d) For reasonable attorneys' fees and costs;

(e) For pre-judgment and post-judgment interest; and

(f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: September 9, 2022

/s/ Paula S. Bliss
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