Baltimore, MD 21215 *

and *

LIFEBRIDGE HEALTH, INC. *
2401 West Belvedere Avenue
Baltimore, MD 21215 *

and *

DAVID B. SILVERMAN *
2435 West Belvedere Avenue, Suite 33
Baltimore, MD 21215 *

Defendants. *

* * * * * * * * * * * * *

COMPLAINT

Teri Chavis (hereinafter the "Plaintiff" or referred to by her maiden name "Teri Payne"), by her attorneys, the Law Offices of Peter G. Angelos, P.C., allege at all relevant times hereinafter mentioned:

I. INTRODUCTION

1. Approximately 600,000 hysterectomies are performed each year in the United States. The laparoscopic power morcellator device (the "Power Morcellator"), originally introduced approximately twenty years ago, is used to perform as many as a 100,000 of these hysterectomies and thousands of myomectomies each year. The Power Morcellator is commonly referred to by manufacturers and physicians as a "minimally invasive" alternative to a vaginal or open abdominal hysterectomy. However, use of the device is far from "minimally invasive" when it causes cancerous or non-malignant tissue to spread with tragic consequences. Power Morcellators are designed with fast-spinning

blades intended to slice, mince, and grind painful uterine growths called fibroids and the uterus itself, which can then be removed through key-hole sized incisions in the abdomen. During this process, the minced tissue and cells are littered throughout the woman's abdominal cavity. It is well-known throughout the medical community that in some women a cancer called leiomyosarcoma masquerades as a fibroid. There is no reliable method to definitively detect leiomyosarcoma before surgery, not even by utilizing the most advanced imaging techniques. The device can also cause non-malignant tissue cells to spread and seed throughout the body, resulting in abnormal growths, and causing the patient extreme pain.

II. PARTIES

2. Plaintiff is an adult individual residing at 3549 North Flint Avenue, Idaho Falls, ID 83401. Plaintiff was a resident of the State of Maryland from 1994 to August 2013.

3. Defendant ETHICON, INC. is a corporation organized and/or existing under the laws of the State of New Jersey, with its principal place of business at 737 U.S. Highway 22, Bridgewater, New Jersey 08807.

4. Defendant ETHICON ENDO-SURGERY, INC. is a corporation organized and/or existing under the laws of the State of Ohio, with its principal place of business at 4545 Creek Road, Blue Ash, Ohio 45242.

5. Defendant ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC. is a corporate division of ETHICON, INC. organized and/or existing under the laws of the State of New Jersey, with its principal place of business at

Route 22 West Somerville, New Jersey 08876.

6. Defendant JOHNSON & JOHNSON SERVICES, INC. is a corporation organized and/or existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

7. Defendant JOHNSON & JOHNSON is a corporation organized and/or existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. On information and belief, Defendant JOHNSON & JOHNSON owns all of the common stock and other ownership interests of Defendants ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC., ETHICON ENDO- SURGERY, INC., and JOHNSON & JOHNSON SERVICES, INC.

9. On information and belief, JOHNSON & JOHNSON is either the direct or indirect owner of substantially all the stock or other ownership interests of ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES.

10. On information and belief, JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES were the agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

11. In doing the acts alleged herein, said Defendants were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy,

predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other (hereinafter JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC., ETHICON ENDO- SURGERY, INC., and JOHNSON & JOHNSON SERVICES are collectively referred to as "JOHNSON & JOHNSON").

12. At all times relevant hereto, DAVID B. SILVERMAN, M.D. was a duly licensed physician holding himself out to the general public as a competent and skillful physician with special training in the field of gynecology and gynecologic surgery and as an individual who would properly monitor, attend to, examine, diagnose, treat, refer, consult upon, and administer to patients who might submit to his care and professional treatment. As such, Health Care Provider DAVID B. SILVERMAN, M.D. owed a duty to the Plaintiff to render that degree of care and treatment which is ordinarily rendered by those who devote special study and attention to the practice of gynecologic surgery, including the full disclosure of all material risks associated with the care and treatment of the Plaintiff. Upon information and belief, DAVID B. SILVERMAN, M.D. is a resident of Baltimore County, Maryland, who at all relevant times carried out the practice of medicine in Baltimore County, Maryland.

13. At all times relevant hereto, LIFEBRIDGE HEALTH, INC. was and is a professional association organized under the laws of the State of Maryland, with its principal place of business at 2401 W. Belvedere Avenue, Baltimore, Maryland. LIFEBRIDGE HEALTH, INC. was at all times relevant hereto, a medical practice offering medical and other related services to the general public. As such, LIFEBRIDGE

HEALTH, INC. its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Plaintiff to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Plaintiff. At all relevant times hereto, Health Care Provider DAVID B. SILVERMAN, M.D. was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of LIFEBRIDGE HEALTH, INC.

14. At all times relevant hereto, SINAI HOSPITAL OF BALTIMORE, INC. was and is a corporation organized under the laws of the State of Maryland, with its principal place of business at 2401 W. Belvedere Avenue, Baltimore, Maryland. SINAI HOSPITAL OF BALTIMORE, INC. was at all times relevant hereto, a medical facility offering medical and other related services to the general public. As such, SINAI HOSPITAL OF BALTIMORE, INC., its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Plaintiff to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Plaintiff. At all relevant times hereto, Health Care Provider DAVID B. SILVERMAN, M.D. was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of SINAI HOSPITAL OF BALTIMORE, INC.

15. On information and belief, Health Care Providers LIFEBRIDGE HEALTH, INC., and SINAI HOSPITAL OF BALTIMORE, INC. were the actual and/or apparent agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

16. In doing the acts alleged herein, Health Care Providers LIFEBRIDGE HEALTH, INC. and SINAI HOSPITAL OF BALTIMORE, INC. were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other.

17. At all relevant times, Health Care Provider DAVID B. SILVERMAN, M.D. was the actual and/or apparent agent, servant, or employee of the Health Care Providers LIFEBRIDGE HEALTH, INC. and SINAI HOSPITAL OF BALTIMORE, INC. and was acting in the course and scope of his duties as such.

18. At all times relevant hereto, TERI PAYNE was a patient of Health Care Providers DAVID B. SILVERMAN, M.D., LIFEBRIDGE HEALTH, INC., and SINAI HOSPITAL OF BALTIMORE, INC., who were therefore under a duty to provide proper, adequate, timely, and acceptable medical care, treatment, information, and advice to her.

19. At all times relevant hereto, all employees and/or agents of each of the Health Care Providers acted within the scope of their authority.

20. On information and belief, at all relevant times, Health Care Providers committed tortious acts within the State of Maryland causing injury within the State of Maryland out of which acts these causes of action arise.

III. JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §1-501. This Court has personal jurisdiction over the Defendants pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §§6-102 and 6-103.

22. The amount of this claim exceeds $30,000, and therefore, jurisdiction lies exclusively in the Circuit Court.

23. Venue is proper in the Circuit Court for Prince George's County pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §§ 6-201, 6-202.

24. Plaintiffs' claims against the Health Care Providers are ripe for determination in this Court as an action was timely instituted in the Health Care Alternative Dispute Resolution Office, and a waiver was filed pursuant to 3-2A-06B of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland.

IV. BACKGROUND AND FACTS COMMON TO ALL COUNTS

A. Plaintiff's Surgery and the Resultant Pelvic Mass

25. Beginning in 2011, Ms. Payne began suffering from heavy menstrual cycles causing her significant pelvic pain. Ms. Payne sought treatment at LifeBridge Medical Center at Mays Chapel, where her midwife, Hilles Whedbee, attempted to alleviate the pain with birth control medication. This treatment was not effective.

26. In or around May 2012, Ms. Payne returned to Hilles Whedbee, who recommended an ablation procedure to treat the pain. An endometrial biopsy performed prior to the ablation procedure, showed complex hyperplasia without atypia.

27. In light of the results of the endometrial biopsy, an ablation procedure was not performed, and Ms. Payne was referred to Dr. David Silverman for consultation.

28. Dr. Silverman recommended a hysterectomy, and strongly encouraged Ms. Payne to agree to a laparoscopic hysterectomy. Dr. Silverman told Ms. Payne that the laparoscopic procedure would allow her to recover faster and would leave a smaller scar than the alternative.

29. Based on Dr. Silverman's counsel, Ms. Payne presented to Sinai Hospital on June 18, 2012, where she underwent a laparoscopic supracervical hysterectomy. This procedure was performed using an Ethicon Morcellex Power Morcellator, which was unbeknownst to Ms. Payne.

30. Prior to this procedure, Dr. Silverman did not communicate all material risks of the procedure that were known to him, including the risk of spreading and seeding malignant and non-malignant tissue, which can lead to painful abnormal and/or recurrent growths within the body. On the day of the procedure, a Sinai Hospital Informed Consent document was provided to Ms. Payne, which not only failed to identify material risks of the procedure, including the risk of spreading and seeding malignant and non-malignant tissue, but also misled Ms. Payne to believe that there were no alternative treatments to the procedure.

31. On June 18, 2012 the laparoscopic hysterectomy by power morcellation was performed.

32. A pathological examination of the tissue removed during the laparoscopic hysterectomy by power morcellation was negative for malignancy but showed proliferative endometrium.

33. Following the procedure using the Power Morcellator, Ms. Payne began suffering from severe chronic and acute pelvic pain associated with her menses.

34. The pain became so severe and debilitating that Ms. Payne went to the emergency room at the Eastern Idaho Regional Medical Center on July 30, 2014.

35. A CT Scan taken revealed a pelvic mass of undetermined significance located near the sigmoid rectal junction.

36. On July 30, 2014, a diagnostic laparoscopy was performed and the pelvic mass was partially resected. The mass could not be completely removed at this time because it was found to be attached the colon.

37. The pathology from the laparoscopy demonstrated that the prior hysterectomy procedure by power morcellation likely caused the fragment to become lodged in the deep pelvis with subsequent adhesion and neovascularization.

38. In or around September 2014, severe pelvic pain again caused Ms. Payne to return to the hospital.

39. On November 4, 2014, Ms. Payne underwent open surgery to resect the remainder of the pelvic mass.

40. Ms. Payne no longer suffers from debilitating pelvic pain, but she has, and will continue to receive, regular monitoring and exams in an attempt to identify any potential recurrence of benign growth in the pelvic region.

B. Background on Laparoscopic Power Morcellators

41. In the United States, over 650,000 women each year will undergo a surgical removal of all or part of the reproductive system and/or fibroids, sometimes including removal of one or both ovaries.

42. In conventional surgeries, the organs remain essentially intact and delivered in that condition from the abdomino-pelvic cavity.

43. In the last few decades, gynecologic surgeons have increasingly performed laparoscopic procedures using a Power Morcellator, like the Morcellex, to remove organs and tissue during abdominal surgeries, including hysterectomies, myomectomies, oophorectomies, and laparotomies.

44. A Power Morcellator is an electrically powered medical device with spinning blades that shred, grind, and core tissue into smaller pieces or fragments inside the patient so the tissue can be removed through small incisions or extraction "ports" in the abdomen.

45. Power Morcellators are designed with a grasper that pulls the tissue up against the sharp, rotating blades, severing the shredded tissue from the rest of the large mass and continuously pulling cut portions of tissue up through the tube.

46. The Power Morcellator's spinning blade shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery.

47. During tissue morcellation, morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs (such as the loops of the bowel),

and cancerous cells can travel to remote areas of the body through the vasculature or lymphatic system.

48. Once disseminated in the body, morcellated fragments can become implanted in surrounding tissue or organs, and begin to grow.

49. When tissue fragments escape into the abdomino-pelvic cavity and seed in other tissue or organs, complications can arise months or years after the surgery.

50. The Johnson & Johnson Defendants were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling Power Morcellators under the following trade names: the Gynecare Morcellex Tissue Morcellator, the Morcellex Sigma Tissue Morcellator System, and the Gynecare X-tract Tissue Morcellator.

C. The Laparoscopic Power Morcellator Used In Plaintiff Surgery Was Defective In Design And Created An Avoidable Risk Of Harm To Plaintiff, Which Caused Her Significant Pain And Suffering And Subsequent Procedures

51. Before Plaintiff underwent surgery in June 2012, the Johnson & Johnson Defendants knew or should have known that their Power Morcellators could cause tissue fragments to be disseminated and implanted in the body.

52. Although evidence was available to the Johnson & Johnson Defendants for years before Plaintiff's June 2012 surgery, the Johnson & Johnson Defendants failed to respond to multiple published studies and reports describing the risk of disseminated material with Power Morcellator use, and failed to design their Power Morcellators, including the the Johnson & Johnson Defendants' Gynecare Morcellex Tissue

Morcellator, in a manner to reduce this life-threatening risk.

53. On information and belief, the Johnson & Johnson Defendants, as is industry practice, daily monitor the medical and lay media for articles on issues concerning their products, Power Morcellators.

54. On information and belief, much, if not all, of the literature cited below was collected by and known to the Johnson & Johnson Defendants (or should have been known to the Johnson & Johnson Defendants) at or before the time the literature was published.

55. The Johnson & Johnson Defendants knew or should have known that their Power Morcellators could cause tissue fragments to be disseminated and implanted in the body.

a. Indeed, on August 6, 1991, a patent for a Surgical Tissue Bag and Method for Percutaneously Debulking Tissue was issued that describes the potential for Power Morcellators to disseminate and implant tissue fragments in the body.

b. The patent for the surgical tissue bag stated:

> "Another problem associated with the debulking, removal or morcellation of large tissue volume is the concern for containing malignant or pathogenic tissue. The morbidity of patients significantly increases when malignant cells of such large volume tissue are permitted to come in contact with surrounding healthy tissue. A malignancy would typically indicate a more invasive procedure in which the cavity is opened and the affected tissue is removed. These invasive open cavity procedures increase the recovery period of the patient and subject the patient to additional discomfort and complications."

c. As a result, the debulking of large malignant tissue volumes percutaneously through an access sheath presents significant morbidity risks to the patient. (emphasis added).The patent Summary of the invention further stated that "containment of the tissue within the bag also prevents the spread of malignant cells to healthy tissue in the body cavity."

d. The Surgical Tissue Bag patent was publically available and was available to the Johnson & Johnson Defendants, and/or known to the Johnson & Johnson Defendants, before they first sought approval of their Power Morcellators.

e. Also, prominent medical journals reporting on Power Morcellators and the risk of spreading undetected cancer also began to accumulate in the 1990s, and continued thereafter.

f. In 1997, Schneider published a case report in a medical journal, known to the Johnson & Johnson Defendants as the American Journal of Obstetrics and Gynecology, titled "Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation," which reported a patient who underwent a laparoscopic supracervical hysterectomy by manual morcellation. Schneider, Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation, J. Am. Obstet. Gynecol., 177(1):478-9 (1997).

g. The following year the patient died due to the rapid progression of uterine adenocarcinoma that had been undetected prior to surgery. *Id.* at 478.

h. Schneider cautioned that evaluation for malignancy prior to surgery "grows even more important and should be mandatory when uteri are increasingly morcellated by introduction of laparoscopic techniques." *Id.* at 479.

i. In 1998, Hutchins and Reinoehl published a case report in The Journal of The American Association of Gynecologic Laparoscopists, which was known to the Johnson & Johnson Defendants, in which the authors explained that "[b]ecause of the large quantity of tissue of such a uterus, it would be anticipated that numerous fragments would be generated during morcellation." Hutchins and Reinoehl, Retained Myoma after Laparoscopic Supracervical Hysterectomy with Morcellation, J. Am. Assoc. Gynecol. Laparosc., 5(3):293-295 (1998).

j. The authors cautioned that the morcellated fragments could become concealed in surrounding organs making it difficult for the surgeon to identify and remove all tissue fragments. *Id.* at 294.

k. Based on this evidence, the Johnson & Johnson Defendants were on notice that their Power Morcellators exposed patients to a significant risk of disseminating and worsening occult cancer.

56. As set forth herein, over the years numerous journal articles and published studies have examined Power Morcellators' potential to spread non-malignant or cancerous tissue, worsening a woman's outcome.

57. This evidence should have placed the Johnson & Johnson Defendants on notice that their Power Morcellators were associated with and/or could cause the dissemination of tissue and worsening a woman's outcome.

58. Yet, as designed and marketed, the Power Morcellator used on Plaintiff during her June 2012 surgery was unsafe for its intended purpose and defective in design in that it subjected the Plaintiff to the avoidable risks of harm, including, inter alia: (a) dissemination and implantation of benign tissue; (b) increasing Plaintiff's probability to develop parasitic or metastatic fibroids; and (c) significantly worsening Plaintiff's outcome.

59. Knowing their Power Morcellators had the potential to spread tissue, the Johnson & Johnson Defendants should have designed, marketed and sold their Power Morcellators, with a containment bag or system specifically designed to minimize or prevent the risk of disseminating tissue.

60. On information and belief, said containment bag or system should have been designed to accommodate and withstand the morcellator blade and the large tissues

that are often encountered in gynecologic surgery.

61. The Johnson & Johnson Defendants' failure to design, develop, manufacture, market and sell the Power Morcellator used in Plaintiff's June 2012 surgery with a containment bag or system to minimize or prevent the risk of disseminating tissue was negligent and fell below the standard of care expected of a reasonable medical device manufacturer.

62. Additionally, at the time of Plaintiff's June 2012 surgery, numerous other treatment options for fibroids were available, which had more established safety profiles and considerably lower risk profiles than Power Morcellators including, but not limited to, total abdominal hysterectomies ("TAH"), minimally-invasive hysterectomies and myomectomies, including those using manual morcellation, and embolization and ablation treatments.

63. Accordingly, for this and the other reasons set forth here and below, the Power Morcellator used in Plaintiff's June 2012 surgery was defective in design.

64. As set forth here and below, the defective design of the Power Morcellator used on Plaintiff during her June 2012 surgery, was the proximate cause of Plaintiff's injuries.

D. The Power Morcellator Used In Plaintiff's Surgery Contained An Inadequate Warning

65. The Johnson & Johnson Defendants failed to provide a reasonable sufficient or adequate warning about the true risks of disseminating tissue from the use of their Power Morcellators.

66. In 1995, the first Power Morcellator reached the market with an indication for gynecologic laparoscopic procedures based on literature involving the device's use in merely 11 patients.

67. Power Morcellators are Class II medical devices.

68. Class II devices are regulated by the Food and Drug Administration Center for Medical Devices and Radiological Health.

69. Such devices are required to undergo a "510(k)" process prior to being distributed, which simply requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), of its intent to market a device at least ninety (90) days prior to the device's introduction on the market, and to explain the device's "substantial equivalence" to a pre-MDA predicate device.

70. Each time the Johnson & Johnson Defendants sought to market a new Power Morcellator device they did so without submitting premarket approval-testing (required under FDA regulations for Class III devices) and merely based on the Johsnon & Johnson Defendants' assertions that the subject device was "substantially similar" to another legally marketed device.

71. Based on the Johnson & Johnson Defendants' assertions that their device was "substantially similar" to a marketed device, the FDA cleared the device for sale in the United States.

72. FDA approval or clearance actions do not guarantee that a product will be

found to be compliant or safe and effective for its intended uses for all times and for all purposes. After the FDA cleared the Power Morcellator used in Plaintiff's June 2012 surgery for sale in the U.S., the Johnson & Johnson Defendants were under an obligation to ensure the quality and safety of their marketed product.

73. The Johnson & Johnson Defendants have an ongoing duty of medical device surveillance and vigilance and were under a continuing duty to inform surgeons, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed devices once that information becomes available to the Johnson & Johnson Defendants.

74. According to the FDA guidance to medical device manufactures, an appropriate Warning should be included if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved. See Device Labeling Guidance #G91-1 - blue book memo, March 8, 1991.

75. However, the Johnson & Johnson Defendants ignored mounting evidence about the cancer risk, and exposed Plaintiff to an avoidable risk of harm by failing to disclose:

a. The difficulty of effectively diagnosing cancer prior to (or during) surgery with available diagnostic tools;

b. The actual prevalence of undiagnosed uterine sarcomas in women undergoing morcellation;

c. The actual rates at which Power Morcellators disseminated and/or upstaged occult cancer;

d. Power Morcellators are associated with worse long-term medical outcomes than other fibroid treatments because of the risk of occult

cancer being spread and implanted by the use of the device;

e. The spread of non-malignant tissue can lead to parasitic or metastatic fibroids; and

f. If cancer is discovered after morcellation, staging and pathological diagnosis could be impeded, thus yielding worse prognosis and outcomes patients.

76. On information and belief, at the time of Plaintiff's June 2012 surgery, the Johnson & Johnson Defendants' instructions for use that accompanied their Power Morcellators, including the Power Morcellator used in performing Plaintiff's June 2012 surgery, contained a "CAUTION" which merely provided: "[a] tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the physician considers to be potentially harmful when disseminated in a body cavity."

77. The device used on Plaintiff failed to contain a Warning or an adequate warning regarding the potential of the Power Morcellator to spread tissue.

78. Likewise, the Power Morcellator used on Plaintiff failed to contain a recommendation to use a tissue extraction bag to minimize the risk of spreading non-malignant tissue.

79. Neither the 510(k) submissions, nor the Johnson & Johnson Defendants' inadequate warnings concerning their Power Morcellators, adequately instructed Plaintiff or her surgeon that an appropriate tissue bag to contain shredded tissue fragments should be used to prevent or minimize the risk of disseminating non-malignant tissue.

80. The Johnson & Johnson Defendants' also failed to adequately warn of the

risks associated with their Power Morcellators including, but not limited to:

a. The failure to adequately warn because any Warnings given were not commensurate with the risks involved;

b. The failure to adequately warn because the Warnings contained no information about the risk of disseminating non-malignant tissue;

c. The failure to timely include a Black Box Warning regarding the risks of disseminating non-malignant tissue; and

d. The failure to timely include a Contraindication regarding the risks of disseminating and upstaging a patient's occult or unknown cancer.

81. The Johnson & Johnson Defendants' failure to timely or appropriately warn of the foregoing risks prevented Plaintiff and her surgeon from fully or correctly evaluating the risks and benefits of undergoing surgery with the Johnson & Johnson Defendants' Power Morcellators.

82. Because of the Johnson & Johnson Defendants failure to adequately warn Plaintiff and her surgeon of the risks associated with Power Morcellator use and the device's propensity to disseminate and upstage or worsen cancer, Plaintiff was caused severe injuries.

83. Because of the Johnson & Johnson Defendants failure to adequately warn Plaintiff and her surgeon of the risks associated with Power Morcellator use and the device's propensity to disseminate, spread and seed tissue causing fibroids to recur, Plaintiff was caused severe injuries.

E. FDA Action And The "World Wide Withdrawal" Of Johnson & Johnson Laparoscopic Power Morcellators In 2014

84. On April 17, 2014, the FDA released a Safety Communication Notice and

Quantitative Assessment to inform health care providers and the public that "based on currently available information, ***the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids***" 4/17/2014 FDA Safety Communication (emphasis added).

85. Upon a review of 18 published and unpublished scientific studies examining patients operated on between 1980 and 2011, the FDA further warned the medical community that:

> "Importantly, based on an FDA analysis of currently available data, it is estimated that ***1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma***, a type of uterine cancer that includes leiomyosarcoma. If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival." Id. (emphasis added).

86. Significantly, in the FDA's "Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids," the FDA listed the studies it relied on in reaching its conclusions on the prevalence of unsuspected uterine sarcoma and uterine leiomyosarcoma.

87. The studies cited by the FDA were published in prominent medical journals, ranging in publication date from 1980 to 2014.

88. Shortly after the FDA released its prevalence data, the Journal of the American Medical Association published the results of Wright et al.'s findings on how many women might have undetected cancer that a Power Morcellator could

unintentionally spread.

89. Wright et al. examined the Perspective Insurance Database, which collects data from over 500 hospitals, to identify women who had a minimally invasive hysterectomy from 2006-2012 with the use of a power morcellator being captured by charge codes. Of the 232,882 women who had minimally invasive surgery during the study period, power morcellation was used in 36,470 surgeries (15.7%). Of these, 99 women were identified as having uterine cancer, for a prevalence of 27/10,000 (95% CI, 22-32/10,000), a prevalence that was positively correlated with patient age, and translates into a 1 in 368 risk of occult malignancy, in keeping with the FDA's Quantitative Assessment, which found a 1 in 352 risk of unsuspected uterine sarcoma.

90. In July 2014, FDA convened an Advisory Committee ("AdCom") meeting of the Obstetrics and Gynecological Medical Device Advisory Committee on Laparoscopic Power Morcellators to discuss, among other topics, "whether a 'boxed warning' related to the risk of cancer spread should be required for laparoscopic power morcellators." Id.

91. In preparation for the AdCom meeting, the FDA prepared an Executive Summary, which detailed the results of the FDA's safety review and stated:

a. The risk of having an unsuspected sarcoma in the population of women undergoing hysterectomy or myomectomy for presumed fibroids may be as high as approximately 1 in 350 for all types of uterine sarcomas, and 1 in 500 for LMS [leiomyosarcoma] specifically.

b. Peritoneal dissemination and/or cancer upstaging (to FIGO Stage III or IV) following morcellation of an unsuspected sarcoma may occur in approximately 25-65% of cases.

c. Patients with unsuspected uterine sarcoma who undergo morcellation may be at significantly higher risk for local (pelvic/abdominal) and overall cancer recurrence compared to those who do not undergo morcellation.

d. Patients with unsuspected sarcoma who undergo morcellation may have poorer disease-free survival and overall survival compared to patients who do not receive morcellation.

92. See Food and Drug Administration Executive Summary, prepared for the July 10-11, 2014 meeting of the Obstetrics and Gynecology Devices Advisory Committee, Laparoscopic Power Morcellation during Uterine Surgery for Fibroids ("FDA Executive Summary"), p. 23.

93. On July 10 and 11, 2014, FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee convened the AdCom meeting on Laparoscopic Power Morcellators. The two-day meeting consisted of presentations from FDA scientists, FDA invited speakers, Power Morcellator manufacturers, and members of the public.

94. During the July 10 and 11, 2014 AdCom meeting, the FDA Panel engaged in a two-day fact-finding expedition to gain a better understanding of the prevalence of unsuspected uterine sarcoma and the risks associated with power morcellation. At the conclusion of the meeting, Panel member, Col. Craig D. Shriver, M.D., a surgical oncologist and Director of the John P. Murtha Cancer Center at Walter Reed National Military Medical Center, stated that "after two days of testimony and data, based on science, . . . there is, at present, no safe way to offer laparoscopic power morcellation as part of any minimally invasive surgery." Dr. Col. Shriver further remarked, "[T]he

power morcellator, should have its Class II device status immediately withdrawn and its use in any laparoscopic surgery banned."

95. Dr. Piet Hinoul, Vice President of Medical Affairs at Defendant Ethicon, Inc., also presented to the Panel on July 10. In so doing, Dr. Hinoul on behalf of the Johnson & Johnson Defendants, made a series of admissions. First, in explaining the Johnson & Johnson Defendants' decision to "suspend global distribution" of its Power Morcellators, Dr. Hinoul admitted that they always knew there was some risk that fibroids were actually occult sarcomas. Dr. Hinoul stated: "[t]he greatest driver in this decision was the higher than previously understood risk of encountering an undiagnosed malignancy, sarcoma in particular, when treating patients with symptomatic fibroids." AdCom Transcript, p. 26. Dr. Hinoul also admitted that "the medical community has long known that power morcellation poses a risk of spreading unsuspected malignant tissue beyond the uterus." AdCom Transcript, p. 27. Finally, Dr. Hinoul admitted that the power morcellator "does what it is intended to do [slice and mince abnormal growths];" however, Dr. Hinoul recognized the problem, stating, "[t]he issue today is the inability to identify certain malignancies . . ." AdCom Transcript , p. 28.

96. Based on the data and literature reviewed, the panel made a number of recommendations on Power Morcellation labeling, including:

a. Power Morcellators should not be used in patients with known or suspected malignancy. See FDA Brief Summary of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Meeting - July 10-11, 2014 ("FDA AdCom Summary Panel Findings") p. 3.

b. A black boxed warning related to the risk of disseminating

unsuspected malignancy during surgeries for presumed benign fibroids would be useful but not enough to address the issue alone. *Id.* (emphasis added).

c. The panel also expressed interest in exploring other ways to ensure that patients have the appropriate information related to the risk, including a mandatory patient consent form to be signed by the patient and physician. *Id.*

97. The AdCom panel also found that the patient populations for which the risks of Power Morcellation may outweigh the benefits were quite limited, noting that several panel members identified peri- or post-menopausal women with symptomatic uterine fibroids. *Id.* at 2-3.

98. Facing mounting negative publicity about its devices spreading cancer, on April 30, 2014, the Johnson & Johnson Defendants suspended worldwide sale of their Power Morcellators.

99. In a "Dear Healthcare Provider" letter, Johnson & Johnson explained:

> "Based on this Safety Communication, in order to align with the FDA's recommendation and Ethicon's internal investigations, Ethicon has decided to suspend global commercialization (sales, distribution, and promotion) of its Morcellation Devices until the role of morcellation for patients with symptomatic fibroid disease is further redefined by FDA and the medical community."

100. In that same letter, the Johnson & Johnson Defendants emphasized that the decision to suspend global commercialization was "not a product removal." *Id.*

101. On July 30, 2014, the Johnson & Johnson Defendants issued an urgent worldwide withdrawal of the Ethicon Morcellators.

102. The Johnson & Johnson Defendants continued to defend their Power Morcellator devices, stating that "Ethicon Morcellation Devices perform as intended and

there are patients who can benefit from procedures using laparoscopic power morcellators, but the risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain."

103. On November 24, 2014, the FDA issued and updated FDA Safety Communication regarding Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy.

104. According to the Safety Communication, the FDA was issuing an Immediately In Effect (IIE) guidance that asked manufacturers of Power Morcellators to include two contraindications and a boxed warning in their product labeling, which warned the medical community against using laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy, and recommends doctors share this information with their patients.

105. The boxed warning informs health care providers and patients that:

> "Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices."

106. The two contraindications advise of the following:

a. Laparoscopic power morcellators are contraindicated (should not be used) for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal, or candidates for en bloc tissue removal (removing tissue intact) through the vagina or minilaparotomy incision. (These groups of women represent the majority of women with fibroids who undergo hysterectomy and

myomectomy.)

b. Laparoscopic power morcellators are contraindicated (should not be used) in gynecologic surgery in which the tissue to be morcellated is known or suspected to be cancerous.

V. CLAIMS FOR RELIEF

COUNT I: NEGLIGENCE
(Johnson & Johnson)

107. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

108. The Johnson & Johnson Defendants were regularly engaged in the business of designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling medical devices known as Power Morcellators for use in gynecological surgery to remove the uterus (hysterectomy) and/or to remove uterine fibroids (myomectomy) in women.

109. The Johnson & Johnson Defendants owed a duty to design, research, develop, test, manufacture, package, label, market, promote, distribute, sell and/or supply products, including gynecologic products used for uterine morcellation, in such a way as to avoid harm to persons upon whom they were used by adequately warning of the hazards and dangers associated with the use of said products.

110. The Johnson & Johnson Defendants also owed a duty to warn of the hazards and dangers associated with the use of its medical devices, including the risk that its Power Morcellators can cause the spread of cancer and non-malignant tissue, and diminish, if not eliminate, a patient's chance of recovery and survival.

111. Upon recognition that their Power Morcellators, were causing the spread of

undetected cancers and non-malignant tissue, and diminishing, if not eliminating, the chance of recovery and survival in patients subjected to these devices, the Johnson & Johnson Defendants had a further duty to remove their Power Morcellators from the marketplace.

112. The Plaintiff was one of the persons the Johnson & Johnson Defendants should reasonably have expected to be affected by their Power Morcellator.

113. The Johnson & Johnson Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were careless, reckless, negligent, grossly negligent and exhibited willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, and/or placing into the stream of commerce, gynecologic products, including Power Morcellators used for uterine morcellation, by:

a. failing to design their Power Morcellators for safe use in fibroid removal surgery;

b. failing to conduct adequate and appropriate testing of their gynecologic products;

c. marketing their Power Morcellators without first conducting adequate research to determine possible side effects on humans or selectively and misleadingly revealing or analyzing testing and research data;

d. failing to monitor registry data regarding their marketed devices and promptly report any safety concerns that arise through registry study or data;

e. failing to keeping abreast of scientific literature and studies which provided the Johnson & Johnson Defendants notice of the risks associated with the use of Power Morcellators;

f. failing to appropriately respond to their own and others testing of,

and information available regarding Power Morcellators, which indicated such products' potential harm to humans;

g. failing to appropriately monitor the post-market performance, adverse events, and complications reported about their Power Morcellators and their products' effects on patients;

h. failing to promptly disseminate new safety information and data regarding their products after their Power Morcellators reached the market;

i. failing to adequately warn of the actual potential of their Power Morcellators to be harmful to humans; (formatting)

j. failing to adequately warn of the actual potential for the dissemination and/or upstaging of metastases of cancer when using Power Morcellators for uterine morcellation;

k. concealing their full knowledge and experience regarding the potential that Power Morcellators were harmful to humans because there was a substantial risk their products would spread cancer;

l. promoting, marketing, advertising and/or selling their Power Morcellators for use for uterine morcellation given their knowledge and experience of such products' potential harmful effects;

m. failing to timely withdraw products used for uterine morcellation from the market, restrict their uses and adequately warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

n. failing to fulfill the standard of care required of a reasonably prudent medical device manufacturer;

o. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of uterine morcellation and its potential harm to humans;

p. failing to provide updated information in the form of reports, statistics and outcomes of studies to physicians, hospitals and other healthcare entities concerning the increased likelihood of cancer dissemination and non-malignant tissue dissemination when such data became available;

q. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

r. advertising and promoting their products used for uterine morcellation as safe and/or safer than other methods of uterine fibroid removal;

s. by improperly submitting 510(k) applications to the FDA that misrepresent their products used for power morcellation of the uterus and fibroids, Gynecare Morcellex Tissue Morcellator, to be "substantially equivalent" to a predicate device, when they had knowledge that the previously cleared Power Morcellator devices were not "substantially equivalent" to tissue punches and other cutting devices;

t. by failing to use due care under the circumstances; and

u. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this case.

114. The Johnson & Johnson Defendants are liable for the actions of their agents and/or employees pursuant to the doctrines of *respondeat superior* and vicarious liability.

115. Despite the fact that the Johnson & Johnson Defendants knew or should have known that their Power Morcellators were associated with and/or caused the dissemination and/or upstaging of unsuspected malignant tissue and non-malignant tissue, the Johnson & Johnson Defendants continued to market, manufacture, distribute, and/or make available their Power Morcellators to patients through their surgeons and/or health care facilities, including the Plaintiff and her surgeon.

116. The Johnson & Johnson Defendants, directly or through their sales staff and/or agents, paid consultants, and/or licensed distributors, among others, made false material representations and/or material omissions through the course of aggressive sales and marketing operations that implemented false and misleading statements by sales

representatives, Defendant-sponsored literature, Defendant-sponsored events and conferences, online and/or video marketing, or other promotional material in order to promote and sell their Power Morcellators while omitting material facts regarding said devices' dangerous side effects and adverse events.

117. The Johnson & Johnson Defendants knew or should have known that consumers, such as the Plaintiff, would foreseeably suffer injury as a result of the Johnson & Johnson Defendants' failure to exercise ordinary care, as set forth above.

118. The Johnson & Johnson Defendants' negligence and/or recklessness was the cause of and substantial factor in bringing about Plaintiff's injuries, harm and economic loss.

119. The Johnson & Johnson Defendants' acted in conscious disregard of, or indifference to, the high degree of risk of physical harm to women undergoing surgery with their Power Morcellators, including Plaintiff, of which the Johnson & Johnson Defendants knew or has reason to know, giving rise to punitive damages.

120. The Johnson & Johnson Defendants knew or should have known of the danger associated with the use of their Power Morcellator as well as the defective nature of said products, but continued to design, manufacture, sell, distribute, market, promote and/or supply their Power Morcellators so as to maximize sales and profits at the expense of the public health and safety.

121. The Johnson & Johnson Defendants are doing business in Maryland.

122. The Johnson & Johnson Defendants carried on solicitation or service actives in Maryland.

123. The Johnson & Johnson Defendants' Power Morcellators were used within Maryland in the ordinary course of trade.

124. The Johnson & Johnson Defendants derived and derive substantial revenue from interstate commerce.

125. As a result of the Johnson & Johnson Defendants' negligence and/or recklessness, Plaintiff was caused to suffer serious and dangerous side effects including the dissemination of non-malignant tissue resulting in physical pain and mental anguish, diminished enjoyment of life, any and all life complications caused by the subsequent procedures.

126. As a foreseeable, direct, and proximate result of the aforementioned negligence by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT II: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN
(Johnson & Johnson)

127. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

128. The Johnson & Johnson Defendants engaged in the design, manufacture, marketing, sale and distribution of products used for power morcellation of the uterus and fibroids, including specifically the Gynecare Morcellex Tissue Morcellator.

129. The Johnson & Johnson Defendants sold the Gynecare Morcellex Tissue Morcellator purchased by Sinai Hospital of Baltimore, and utilized by Dr. Silverman in performing a hysterectomy with fibroid removal on the Plaintiff.

130. The Johnson & Johnson Defendants' Power Morcellator was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were designed, produced, manufactured, labeled, sold, distributed, and/or marketed by the Johnson & Johnson Defendants.

131. The Johnson & Johnson Defendants' Power Morcellator was defective in design or formulation in that it was not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design.

132. The Johnson & Johnson Defendants' Power Morcellator was defective in design or formulation in that it lacked efficacy, posed a greater likelihood of injury and was more dangerous than other available surgical treatment options indicated for the same conditions and uses, including those discussed above.

133. The Johnson & Johnson Defendants' Power Morcellator was defective in design or formulation in that when it left the hands of the manufacturers and/or suppliers, the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, including those discussed above, which had more established safety profiles and a considerably lower risks, or by the provision of reasonable instructions or warnings.

134. The Johnson & Johnson Defendants' Power Morcellator, as designed, posed a substantial and avoidable likelihood of harm and it was feasible to design said products in a safer manner.

135. The Johnson & Johnson Defendants' Power Morcellator was defective in design or formulation in that the dangers associated with its use was unknowable and unacceptable to the average or ordinary consumer.

136. The Johnson & Johnson Defendants' Power Morcellator failed to comply with state and federal standards when sold.

137. At the time of Plaintiff's June 2012 surgery, the Power Morcellator was being used for its advertised and intended purpose, and in the manner the Johnson & Johnson Defendants intended.

138. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of the Johnson & Johnson Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

139. Due to the aforesaid condition of the Power Morcellator used on Plaintiff during her June 2012 surgery, the Johnson & Johnson Defendants are strictly liable to

Plaintiffs.

140. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Johnson & Johnson)

141. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

142. The Johnson & Johnson Defendants were under an ongoing duty to keep abreast of medically known or knowable information related to their products and to advise clinicians of these risks in a timely manner to ensure the safe use of their product.

143. The Johnson & Johnson Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her surgeon, of the following risks

associated with the use of their Power Morcellators, all of which were known or scientifically knowable to the Johnson & Johnson Defendants prior to the date on which the Plaintiff underwent her June 2012 surgery, including, but not limited to:

a. the risk of aggressively disseminating unsuspected malignant or non-malignant tissue beyond the uterus;

b. the device's risk of upstaging a patient's undetected or occult cancer;

c. failing to provide accurate warnings regarding the inadequacy of pre-operative screening for the presence of unsuspected malignant uterine tissue in women;

d. failing to provide accurate rates of the prevalence of unsuspected malignant tissue in women undergoing uterine morcellation; and

e. failing to advise doctors to carefully monitor patients following Power Morcellator surgery to evaluate for the presence of uterine cancer, additional benign tumors, and parasitic myomas at an earlier date and to allow for appropriate treatment in the event of such a finding.

144. The Johnson & Johnson Defendants' failure to adequately warn Plaintiff and her surgeon of the risks associated with Power Morcellators prevented Plaintiff and her surgeon from correctly and fully evaluating the risks and benefits of undergoing surgery with the Johnson & Johnson Defendants' device.

145. The Johnson & Johnson Defendants failed to timely include a Black Box Warning regarding the risks of dissemination of non-malignant tissue or occult malignancy and the upstaging of a patient's occult cancer.

146. The Johnson & Johnson Defendants failed to timely include a Contraindication that Power Morcellators should not be used in women with tissue of unsuspected, occult, or unknown malignancy.

147. Had the Johnson & Johnson Defendants timely and adequately warned of the risks of the Power Morcellator used during Plaintiff's June 2012 surgery, such warnings would have been heeded by Plaintiff's surgeon, in that Plaintiff's surgeon would have changed the manner in which he prescribed or selected the Power Morcellator for Plaintiff's June 2012 surgery, including but not limited to, communicating the risks to the Plaintiff prior to her June 2012 surgery, not using the Power Morcellator, and/or selecting an alternative and safer treatment option for Plaintiff.

148. If Plaintiff had been adequately warned of the life-threatening risks of the use of the Power Morcellator, as stated herein, she would have chosen an alternative treatment, one that did not carry the avoidable risks of disseminating and/or upstaging occult cancer and disseminating non-malignant tissue enabling it to form growths throughout her body and, therefore, would have avoided the injuries described herein.

149. The Johnson & Johnson Defendants' failure to adequately warn about the risk of their Power Morcellators was a substantial and contributing factor in causing Plaintiff's injuries.

150. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT IV: BREACH OF WARRANTY – EXPRESS WARRANTIES
(Johnson & Johnson)

151. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

152. The Johnson & Johnson Defendants expressly warranted through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their Power Morcellators were safe, and withheld and concealed information from Plaintiff and her surgeon about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation.

153. The Johnson & Johnson Defendants expressly warranted that their Power Morcellators were safe for their intended use and as otherwise described in this Complaint.

154. The Power Morcellator used on Plaintiff during her June 2012 surgery did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient studies, the representation that it was safe for use, the representation that it did not have high and/or unacceptable levels of life-

threatening side effects, and that it would improve or maintain health, and potentially prolong life.

155. The Johnson & Johnson Defendants represented that the products used for uterine morcellation were safer and more efficacious than other alternative surgical approaches and techniques.

156. The Johnson & Johnson Defendants further concealed information, regarding the true efficacy of said products.

157. The Johnson & Johnson Defendants' Power Morcellators failed to conform to the foregoing express representations because their devices were not safe or effective, could produce serious side effects, including among other things disseminating malignant and non-malignant tissue beyond the uterus and/or upstaging or worsening cancer and degrading Plaintiff's health.

158. The Johnson & Johnson Defendants made these material representations, which also included omissions of material fact, to the medical and healthcare community at large, the general public, to Plaintiff's medical or healthcare provider(s), and/or to Plaintiff with intent to induce medical and healthcare providers and patients to dispense, provide, prescribe, accept, and/or purchase their Power Morcellators.

159. The Johnson & Johnson Defendants made false material representations and/or material omissions through the course of an aggressive sales and marketing operation that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, and/or Defendant-sponsored promotional functions in order to promote and sell their Power Morcellators while omitting material facts

regarding said devices' dangerous side effects and adverse events.

160. The express warranties represented by the Johnson & Johnson Defendants were a part of the basis for her surgeon's consent to permit the use of the Power Morcellator on Plaintiff during her June 2012 surgery.

161. Plaintiff's surgeon relied on said express warranties in deciding to use the Power Morcellator as a treatment option.

162. At the time of the making of the express warranties, the Johnson & Johnson Defendants had knowledge of the purpose for which their Power Morcellators were to be used, and expressly warranted the same to be in all respects safe, effective and proper for such purpose.

163. As a foreseeable, direct, and proximate result of the aforementioned Breach of Express Warranties by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT V: BREACH OF IMPLIED WARRANTY – PARTICULAR PURPOSE
(Johnson & Johnson)

164. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

165. The Johnson & Johnson Defendants impliedly represented and warranted to the users of their Power Morcellators and patients undergoing surgery with their Power Morcellators that said devices was safe and fit for the particular purpose for which said products were to be used, namely for the safe removal of uterine tissue and uterine fibroids.

166. These aforementioned representations and warranties were false, misleading, and inaccurate in that the Johnson & Johnson Defendants' Power Morcellators were unsafe and harmed Plaintiff.

167. Plaintiff's physician relied on the implied warranty of fitness for a particular use and purpose.

168. Plaintiff's surgeon reasonably relied upon the skill and judgment of the Johnson & Johnson Defendants as to whether the Johnson & Johnson Defendants' Power Morcellator was safe and fit for its intended use (hysterectomies and myomectomies, among other indications).

169. The Johnson & Johnson Defendants' Power Morcellators were placed into the stream of commerce by the Johnson & Johnson Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without

substantial change in the condition in which they were sold.

170. The Johnson & Johnson Defendants breached the aforesaid implied warranty, as their Power Morcellators, including the Power Morcellator used on Plaintiff, were not reasonably fit for their intended purposes and uses.

171. As a foreseeable, direct, and proximate result of the aforementioned Breach of Implied Warranties – Particular Purpose, by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT VI: BREACH OF IMPLIED WARRANTY – MERCHANTABILITY
(Johnson & Johnson)

172. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

173. The Johnson & Johnson Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold their Power

Morcellators for the purpose of removing uterine tissue.

174. The Johnson & Johnson Defendants knew and promoted the use of their Power Morcellators for the use for which said device was to be used on the Plaintiff, namely treating uterine fibroids, improving health, maintaining health, and potentially prolonging life.

175. The Johnson & Johnson Defendants impliedly warranted to Plaintiff and her surgeon that their Power Morcellators were of merchantable quality for the purposes for which they were to be used.

176. These aforementioned representations and warranties were false, misleading, and inaccurate in that the Power Morcellator used on Plaintiff was unsafe, degraded Plaintiff's health.

177. Plaintiff and her surgeon reasonably relied on the skill, expertise and judgment of the Johnson & Johnson Defendants and their representations as to the fact that the Power Morcellator selected for and used on Plaintiff was of merchantable quality.

178. Said Power Morcellators were not of merchantable quality, in that said devices had dangerous and life threatening side effects and; thus, were not fit for the ordinary purpose for which they was intended.

179. As a foreseeable, direct, and proximate result of the aforementioned Breach of Implied Warranties – Merchantability, by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT VII: CONSUMER PROTECTION ACT
(Johnson & Johnson)

180. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

181. The Maryland Consumer Protection Act (hereinafter the "MCPA"), Md. Code Ann., Com. Law Art. §13-301 et. seq., applies to the Johnson & Johnson Defendants' actions and conduct described herein because it extends to transactions which are intended to result, of which have resulted, in the sale of goods to consumers.

182. The Johnson & Johnson Defendants sold and continue to sell medical devices in Maryland, and therefore, qualify as a merchant within the meaning of Md. Code Ann., Com, Law Art. §13-101(g).

183. Plaintiff was a "consumer" within the meaning of the MCPA.

184. Plaintiff purchased (directly, or through her surgeon, and/or the heath care facility at which her June 2012 surgery was performed) primarily for personal use the laparoscopic Power Morcellator used on her during her June 2012 surgery and, thereby,

suffered ascertainable losses as a result of the Johnson & Johnson Defendants' actions in violation of the consumer protection laws.

185. On information and belief, said purchase occurred in the State of Maryland.

186. The Johnson & Johnson Defendants have violated and continue to violate the MCPA in representing that goods have characteristics and benefits which they do not have.

187. Had the Johnson & Johnson Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the laparoscopic Power Morcellator that was used on her during her June 2012 surgery (directly, or through her surgeon, and/or the heath care facility at which her June 2012 surgery was performed), and would not have incurred related medical costs and injury.

188. The Johnson & Johnson Defendants engaged in knowingly wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff for the Power Morcellator that was used on her during her June 2012 laparoscopic surgery, that would not have been paid had the Johnson & Johnson Defendants not engaged in such unfair and deceptive conduct.

189. The untrue, misleading, and/or deceptive assertions, representations or statements of fact regarding Power Morcellators were made by the Johnson & Johnson Defendants to the public in promotional materials, Defendant-sponsored medical literature, videos, Defendant-sponsored presentations, and/or face-to-face sales calls with the Johnson & Johnson Defendants' sales representatives and/or agents, with the intent to induce an obligation.

190. Plaintiff and her surgeon and medical care providers justifiably relied on the untrue, misleading, and/or deceptive assertions, representations or statement of fact made by the Johnson & Johnson Defendants to the public in promotional materials, Defendant-sponsored medical literature, videos, Defendant-sponsored presentations, and/or face-to-face sales calls regarding Power Morcellators, in selecting the Gynecare Tissue Morcellator, for use in Plaintiff's June 2012 surgery.

191. Plaintiff was injured by the cumulative and indivisible nature of the Johnson & Johnson Defendants' conduct. The cumulative effect of the Johnson & Johnson Defendants' conduct directed at patients, physicians and consumers was to create demand for and to sell their Power Morcellator devices. Each aspect of the Johnson & Johnson Defendants' conduct combined to artificially create sales of said products.

192. The Johnson & Johnson Defendants had actual knowledge of the defective and dangerous condition of the products and failed to take any action to cure such defective and dangerous condition.

193. Reasonable consumers, including Plaintiff, were injured by the Johnson & Johnson Defendants' unfair and deceptive acts.

194. The Johnson & Johnson Defendants' failure to inform Plaintiff and/or Plaintiff's medical providers of the risks and hazards associated with the use of the Power Morcellator was deceptive and was a violation of the MCPA, Md. Code Ann., Com. Law Art. §13-301(3), and constitutes an unfair and deceptive trade practice in violation of §13-303 of the MCPA.

195. As a foreseeable, direct, and proximate result of the aforementioned violations of the MCPA by the Johnson & Johnson Defendants, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT VIII: FRAUD - INTENTIONAL MISREPRESENTATION
(Johnson & Johnson)

196. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

197. The Johnson & Johnson Defendants, who engaged in the design, manufacture, marketing, sale and distribution of products used for power morcellation of the uterus and fibroids, including specifically the Gynecare Morcellex Tissue Morcellator, owed a duty to provide accurate and complete information regarding said device.

198. Prior to Plaintiff's June 2012 surgery, the Johnson & Johnson Defendants

fraudulently misrepresented the use of their Power Morcellators, Gynecare Morcellex Tissue Morcellator, as safe and effective, as described in Paragraphs 51 through 106 herein.

199. The Johnson & Johnson Defendants knew that its misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive and deceitful when they were made.

200. The Johnson & Johnson Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Plaintiff and Plaintiff's medical providers with the intention of having them act and rely on such misrepresentations and/or omissions.

201. Plaintiff and Plaintiff's surgeon relied with reasonable justification, on the misrepresentations and/or omissions by the Johnson & Johnson Defendants, which induced Plaintiff's medical providers to purchase and use the Power Morcellator used in Plaintiff's June 2012 surgery.

202. The Johnson & Johnson Defendants profited, significantly, from their unethical and illegal conduct that fraudulently induced Plaintiff's medical providers to purchase a dangerous and defective product.

203. The Johnson & Johnson Defendants' actions, and Plaintiff's and Plaintiff's medical providers' justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

204. As a foreseeable, direct, and proximate result of the aforementioned fraudulent misrepresentations by the Johnson & Johnson Defendants, Plaintiff sustained

the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT IX: FRAUD - CONCEALMENT
(Johnson & Johnson)

205. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

206. The Johnson & Johnson Defendants owed Plaintiff and Plaintiff's medical providers duties to fully and accurately disclose all material facts regarding their Power Morcellator devices, including specifically the Gynecare Morcellex Tissue Morcellator, not to conceal material defects related thereto, not to place these defective devices within the stream of commerce, and to fully and accurately label its product packaging. To the contrary, the Johnson & Johnson Defendants explicitly and/or implicitly represented that their Power Morcellators, including the Gynecare Morcellex Tissue Morcellator, were safe and effective.

207. The Johnson & Johnson Defendants actively and intentionally concealed and/or suppressed material facts, referenced in Paragraphs 51 through 106 herein, in whole or in part, to induce Plaintiff's medical providers to purchase and use their Power Morcellators, including Gynecare Morcellex Tissue Morcellator, and did so at the expense of and risk to Plaintiff.

208. The Johnson & Johnson Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Plaintiff and Plaintiff's medical providers and with the intention of having Plaintiff and Plaintiff's medical providers act and rely on such misrepresentations and/or omissions.

209. The Johnson & Johnson Defendants knew that their, concealment, misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, The Johnson & Johnson Defendants concealed information, and/or made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.

210. The Johnson & Johnson Defendants profited, significantly, from their unethical and illegal conduct that caused Plaintiff and/or Plaintiff's medical providers to purchase a dangerous and defective product.

211. The Johnson & Johnson Defendants actions, and Plaintiff's and Plaintiff's medical providers' justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

212. As a foreseeable, direct, and proximate result of the aforementioned fraudulent concealment by the Johnson & Johnson Defendants, Plaintiff sustained the

following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand judgment against the Johnson & Johnson Defendants for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT X: INFORMED CONSENT – NEGLIGENCE
(David Silverman, LifeBridge Health, Sinai Hospital)

213. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

214. At all times relevant hereto, Dr. Silverman was employed by or was otherwise an actual or apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc.

215. On June 18, 2012, Dr. Silverman performed a supracervical laparoscopic hysterectomy on Plaintiff using a Morcellex power morcellator.

216. The June 2012 laparoscopic surgery was performed at Sinai Hospital of Baltimore, Inc.

217. The laparoscopic surgical procedure involved the use of the Power Morcellator to shred, grind, and disseminate benign tissue inside the uterine cavity.

218. Before performing the June 2012 surgery by power morcellation, Dr. Silverman knew or should have known:

a. that the morcellation procedure presented a material risk of disseminating tissue, malignant and non-malignant, throughout the Plaintiff's body;

b. that the morcellation procedure presented a material risk of causing any disseminated tissue to seed, grow, and/or recur in other parts of the body;

c. that if this benign tissue would spread, seed, recur, and grow in other parts of the body, it would cause abdominal pain and necessitate additional surgical treatment;

d. that the morcellation procedure would result in a more difficult and incomplete pathological diagnosis; and

e. that alternatives existed that would minimize or negate the risk of spreading and seeding malignant and non-malignant tissues in the uterine cavity and throughout Plaintiff's body.

219. Dr. Silverman owed Plaintiff a duty to disclose all material risks associated with the surgical procedure prior to performing said procedure, including those material risks stated in the preceding paragraph.

220. Before the June 2012 surgery was performed, Dr. Silverman failed to properly disclose any of the foregoing material risks to Plaintiff.

221. Before the June 2012 surgery was performed, Dr. Silverman failed to mention, let alone explain, the term "Power Morcellator" to Plaintiff, nor did Dr.

Silverman inform Plaintiff that he would be cutting, grinding and/or mincing the tissue within the Plaintiff's body.

222. Before the June 2012 surgery was performed, the only information verbally communicated to Plaintiff, by Dr. Silverman or any other person, was that the June 2012 surgery would be laparoscopic, which would enable a faster recovery and a smaller scar.

223. Before the June 2012 surgery, Plaintiff signed a Sinai "Consent for operation or other procedure," which was supplied to her by Dr. Silverman. The consent form, signed by Dr. Silverman and Plaintiff, does not disclose any of the material risks stated in Paragraph 218.

224. Furthermore, the consent form provided to Plaintiff misled the Plaintiff to believe she had no choice but to under the laparoscopic hysterectomy by power morcellation. The "Consent for operation or other procedure" stated: "The following alternatives, including no treatment, have been discussed with me. No procedure."

225. Dr. Silverman knew, or in the exercise of reasonable surgical care should have known, that Plaintiff wanted to know of all material risks associated with the surgical procedure prior to undergoing the June 2012 surgery.

226. Contrary to the accepted standards of medical and surgical care, Dr. Silverman failed to inform Plaintiff of the potential material risks associated with the surgical procedure.

227. By failing to inform Plaintiff of the nature and seriousness of the risks stated in Paragraph 218, Dr. Silverman breached his duty to secure the fully informed consent of Plaintiff prior to commencing the operative procedure.

228. If Plaintiff would have been aware of the serious risks involved with the laparoscopic surgical procedure using the Power Morcellator, she would not have consented to it.

229. As a result of the unnecessary procedure for which there was not fully informed consent given by Plaintiff, the Plaintiff suffered recurrent and chronic pelvic pain which required multiple surgeries to resect the masses caused by the spread of tissue as a result of the use of the Power Morcellator.

230. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are liable for the actions of their agents and/or employees, including Dr. Silverman, pursuant to the doctrines of *respondeat superior* and vicarious liability.

231. As a foreseeable, direct, and proximate result of the aforementioned lack of informed consent by the Health Care Providers, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiff demands compensatory damages against LifeBridge Health, Inc., Sinai Hospital of Baltimore, Inc., and health care provider David B. Silverman, M.D. for compensatory damages in excess of $75,000 dollars plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be

determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT XI: INFORMED CONSENT- NEGLIGENCE – APPARENT AGENCY
(LifeBridge Health, Sinai Hospital)

232. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

233. At all times herein relevant, Dr. Silverman was acting as the apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. with regard to the care and treatment of Plaintiff. At those times, Plaintiff was under the reasonable belief that Dr. Silverman was acting under the control, supervision and/or authority of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. and that each held itself out to the public and to the Plaintiff in particular as a full service facility capable of providing competent medical care to patients admitted to its facility. Additionally, Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. did not take any affirmative measures to advise Plaintiff that Dr. Silverman was not acting as an employee, agent and/or representative in connection with the care and treatment of Plaintiff. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are vicariously liable for the negligence of their apparent agents, servants and employees.

234. As a foreseeable, direct, and proximate result of the aforementioned lack of informed consent by the Health Care Providers, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiff demands compensatory damages against Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. in excess of $75,000 dollars plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT XII: FRAUD- NON DISCLOSURE
(David Silverman, LifeBridge Health, Sinai Hospital)

235. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

236. Health Care Providers owed Plaintiff a duty to fully and accurately disclose all material information and risks regarding the laparoscopic hysterectomy using power morcellation.

237. As Plaintiff's physician and surgeon, Dr. Silverman owed Plaintiff a fiduciary duty to disclose all material information related to her health and well-being and any treatment or procedures related thereto.

238. Health Care Providers breached their duties owed to Plaintiff by failing to disclose the material information and risks associated with the surgical procedure performed on June 18, 2012, by power morcellation, as more fully specified in Paragraph 218 of this complaint.

239. Health Care Providers also breached their duties by misrepresenting to Plaintiff that her only alternative was to have "no procedure" done.

240. Health Care Providers knew that their omissions were material, and that their representations about the laparoscopic hysterectomy by power morcellation were false, incomplete, misleading, deceptive, and/or deceitful when they were made. Alternatively, Health Care Providers made the representations with such reckless disregard for the truth that knowledge of the falsity of the representations can be imputed to Health Care Providers.

241. Health Care Providers made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Plaintiff and with the intention of having Plaintiff act and rely on them because the laparoscopic procedure require less resources to perform than the safer, more appropriate, total abdominal surgery alternative and/or because a greater financial benefit would be derived from using the Power Morcellator during laparoscopic surgery.

242. Plaintiff relied with justification on the misrepresentations and omissions by Health Care Providers, which caused Plaintiff to undergo the June 2012 surgery using the Power Morcellator without knowledge of all material risks.

243. Health Care Providers' actions, and Plaintiff's justifiable reliance, caused and/or was a substantial contributing factor in causing Plaintiff to suffer severe injuries and to incur substantial and permanent damages.

244. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are liable for the actions of their agents and/or employees, including Dr. Silverman, pursuant to the doctrines of *respondeat superior* and vicarious liability.

245. As a foreseeable, direct, and proximate result of the aforementioned fraudulent non-disclosure by the Health Care Providers, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiff demands judgment against the Health Care Providers for compensatory damages in excess of $75,000 plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT XIII: FRAUD- NON DISCLOSURE – APPARENT AGENCY
(LifeBridge Health, Sinai Hospital)

246. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

247. At all times herein relevant, Dr. Silverman was acting as the apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. with regard to the care and treatment of Plaintiff. At those times, Plaintiff was under the reasonable belief that

Dr. Silverman was acting under the control, supervision and/or authority of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. and that each held itself out to the public and to the Plaintiff in particular as a full service facility capable of providing competent medical care to patients admitted to its facility. Additionally, Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. did not take any affirmative measures to advise Plaintiff that Dr. Silverman was not acting as an employee, agent and/or representative in connection with the care and treatment of Plaintiff. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are vicariously liable for the negligence of their apparent agents, servants and employees.

248. As a foreseeable, direct, and proximate result of the aforementioned fraudulent non-disclosure by the Health Care Providers, Plaintiff sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

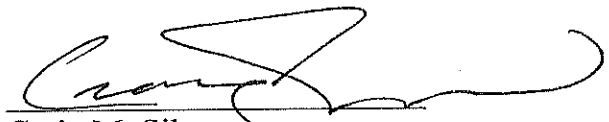
b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiff demands compensatory damages against Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. in excess of $75,000 dollars plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

Dated: December 23, 2015

Respectfully submitted,

LAW OFFICES OF PETER G. ANGELOS, P.C.



Craig M. Silverman
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One Charles Center
100 N. Charles Street, 22nd Floor
Baltimore, Maryland 21201
(410) 649-2000
(410) 640-2101 (fax)
csilverman@lawpga.com

TERI CHAVIS 3549 North Flint Ave. Idaho Falls, Idaho 83401	*	BEFORE THE
	*	HEALTH CARE
Claimant,	*	ALTERNATIVE DISPUTE
v.	*	RESOLUTION OFFICE
LIFEBRIDGE HEALTH, INC., et al.,	*	OF MARYLAND
	*	HCADRO No. 2015-647
Health Care Providers.	*	

* * * * * * * * * * * * *

ORDER OF TRANSFER

The Claimant, by and through counsel, having elected a Waiver of Arbitration under the provisions of Annotated Code of Maryland, Courts and Judicial Proceedings, Article, § 3-2A-06B, it is the 4th day of June, 2015, by the Health Care Alternative Dispute Resolution Office,

ORDERED, that this case shall be and is hereby, transferred to the United States District Court, or to the Circuit Court of the appropriate venue.

HARRY E. CHASE, DIRECTOR
Health Care Alternative Dispute Resolution Office

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that copies of the above ORDER OF TRANSFER have been mailed, postage prepaid, to all counsel.

HARRY L. CHASE, DIRECTOR

HEALTH CARE ALTERNATIVE DISPUTE RESOLUTION OFFICE
6 St. Paul Street, Suite 1501
Baltimore, Maryland 21202-1608
(410) 767-8200

(2)
CLAIM FORM HCA NO.: _____

CLAIMANT(S)

Teri Chavis
Name
3549 North Flint Ave.
~~Idaho Falls, ID~~ 83401
Street Address

City, State, Zip Code

Name

Street Address

City, State, Zip Code

Name

Street Address

City, State, Zip Code

RECEIVED
DEC 08 2015
HEALTH CARE
ALTERNATIVE DISPUTE
RESOLUTION OFFICE

HEALTH CARE PROVIDER(S)

Lifebridge Health, Inc.
Name
2401 West Belvedere Avenue
Street Address
Baltimore, MD 21215
City, State, Zip Code

Sinai Hospital of Baltimore, Inc.
Name
2401 West Belvedere Avenue
Street Address
Baltimore, MD 21215
City, State, Zip Code

David B. Silverman
Name
2435 West Belvedere Avenue, Suite 33
Street Address
Baltimore, MD 21215
City, State, Zip Code

(1) This claim is filed pursuant to Title 3, Subtitle 2A of the Courts Article. The damages claimed are in excess of $30,000.00, and the appropriate venue is: Baltimore City, Maryland.

(2) The basis of the claim is described on the page(s) attached hereto.

(3) The resolution of the claim will involve particular expertise in this area of specialty 057 & 005.
(PLEASE SEE REVERSE SIDE FOR AREAS OF CONCENTRATION)

WARNING: Each Claimant has been advised that he/she may be held civilly liable for part or all the Costs resulting from the filing of this claim, whether it is won or lost; this would be an individual and personal responsibility.

ATTORNEY FOR ~~CLAIMANT~~(S)

Signature Craig M. Silverman, Esq.

100 N. Charles Street, 22nd Fl.
Street Address

Baltimore, Maryland 21201
City, State, Zip Code

(410) 649-2087
Telephone Number

CLAIMANT(S)

Teri Chavis
Signature for each Claimant

TERI CHAVIS 3549 North Flint Avenue Idaho Falls, ID 83401 Claimant, v. LIFEBRIDGE HEALTH, INC. 2401 West Belvedere Avenue Baltimore, MD 21215 and SINAI HOSPITAL OF BALTIMORE, INC. 2401 West Belvedere Avenue Baltimore, MD 21215 and DAVID B. SILVERMAN 2435 West Belvedere Avenue, Suite 33 Baltimore, MD 21215 Health Care Providers.	*	BEFORE THE HEALTH CARE ALTERNATIVE DISPUTE RESOLUTION OFFICE OF MARYLAND HCADRO No. _____

* * * * * * * * * * * * *

STATEMENT OF CLAIM

Teri Chavis (hereinafter the "Claimant" or referred to by her maiden name "Teri Payne"), by her attorneys, the Law Offices of Peter G. Angelos, P.C., sue Health Care Providers, David B. Silverman, M.D., Lifebridge Health, Inc., and Sinai Hospital of Baltimore, Inc., and for reasons say:

I. INTRODUCTION

1. Approximately 600,000 hysterectomies are performed each year in the United States. The laparoscopic power morcellator device (the "Power Morcellator"), originally introduced approximately twenty years ago, is used to perform as many as a 100,000 of these hysterectomies and thousands of myomectomies each year. The Power Morcellator is commonly referred to by manufacturers and physicians as a "minimally invasive" alternative to a vaginal or open abdominal hysterectomy. However, use of the device is far from "minimally invasive" when it causes cancerous or non-malignant tissue to spread with tragic consequences. Power Morcellators are designed with fast-spinning blades intended to slice, mince, and grind painful uterine growths called fibroids and the uterus itself, which can then be removed through key-hole sized incisions in the abdomen. During this process, the minced tissue and cells are littered throughout the woman's abdominal cavity. It is well-known throughout the medical community that in some women a cancer called leiomyosarcoma masquerades as a fibroid. There is no reliable method to definitively detect leiomyosarcoma before surgery, not even by utilizing the most advanced imaging techniques. The device can also cause non-malignant tissue cells to spread and seed throughout the body, resulting in abnormal growths, and causing the patient extreme pain.

II. PARTIES

2. Claimant is an adult individual residing at 3549 North Flint Avenue, Idaho Falls, ID 83401. Claimant was a resident of the State of Maryland from 1994 to August 2013.

3. At all times relevant hereto, DAVID B. SILVERMAN, M.D. was a duly licensed physician holding himself out to the general public as a competent and skillful physician with special training in the field of gynecology and gynecologic surgery and as an individual who would properly monitor, attend to, examine, diagnose, treat, refer, consult upon, and administer to patients who might submit to his care and professional treatment. As such, Health Care Provider DAVID B. SILVERMAN, M.D. owed a duty to the Claimant to render that degree of care and treatment which is ordinarily rendered by those who devote special study and attention to the practice of gynecologic surgery, including the full disclosure of all material risks associated with the care and treatment of the Claimant. Upon information and belief, DAVID B. SILVERMAN, M.D. is a resident of Baltimore County, Maryland, who at all relevant times carried out the practice of medicine in Baltimore County, Maryland.

4. At all times relevant hereto, LIFEBRIDGE HEALTH, INC. was and is a professional association organized under the laws of the State of Maryland, with its principal place of business at 2401 W. Belvedere Avenue, Baltimore, Maryland. LIFEBRIDGE HEALTH, INC. was at all times relevant hereto, a medical practice offering medical and other related services to the general public. As such, LIFEBRIDGE HEALTH, INC. its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Claimant to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Claimant. At all relevant

times hereto, Health Care Provider DAVID B. SILVERMAN, M.D. was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of LIFEBRIDGE HEALTH, INC.

5. At all times relevant hereto, SINAI HOSPITAL OF BALTIMORE, INC. was and is a corporation organized under the laws of the State of Maryland, with its principal place of business at 2401 W. Belvedere Avenue, Baltimore, Maryland. SINAI HOSPITAL OF BALTIMORE, INC. was at all times relevant hereto, a medical facility offering medical and other related services to the general public. As such, SINAI HOSPITAL OF BALTIMORE, INC., its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Claimant to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Claimant. At all relevant times hereto, Health Care Provider DAVID B. SILVERMAN, M.D. was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of SINAI HOSPITAL OF BALTIMORE, INC.

6. On information and belief, Health Care Providers LIFEBRIDGE HEALTH, INC., and SINAI HOSPITAL OF BALTIMORE, INC. were the actual and/or apparent agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

7. In doing the acts alleged herein, Health Care Providers LIFEBRIDGE HEALTH, INC. and SINAI HOSPITAL OF BALTIMORE, INC. were acting in the

course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other.

8. At all relevant times, Health Care Provider DAVID B. SILVERMAN, M.D. was the actual and/or apparent agent, servant, or employee of the Health Care Providers LIFEBRIDGE HEALTH, INC. and SINAI HOSPITAL OF BALTIMORE, INC. and was acting in the course and scope of his duties as such.

9. At all times relevant hereto, TERI PAYNE was a patient of Health Care Providers DAVID B. SILVERMAN, M.D., LIFEBRIDGE HEALTH, INC., and SINAI HOSPITAL OF BALTIMORE, INC., who were therefore under a duty to provide proper, adequate, timely, and acceptable medical care, treatment, information, and advice to her.

10. At all times relevant hereto, all employees and/or agents of each of the Health Care Providers acted within the scope of their authority.

11. On information and belief, at all relevant times, Health Care Providers committed tortious acts within the State of Maryland causing injury within the State of Maryland out of which acts these causes of action arise.

III. JURISDICTION AND VENUE

12. Jurisdiction is proper in the Health Claims Alternative Dispute Resolution Office of Maryland as this action arises out of the provision of health care and the amount of this claim greatly exceeds the limits of the concurrent jurisdiction of the District Court of Maryland.

13. Venue is proper in the Circuit Court for Baltimore City pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §§ 6-201, 6-202.

IV. BACKGROUND AND FACTS COMMON TO ALL COUNTS

A. Claimant's Surgery and the Resultant Pelvic Mass

14. Beginning in 2011, Ms. Payne began suffering from heavy menstrual cycles causing her significant pelvic pain. Ms. Payne sought treatment at LifeBridge Medical Center at Mays Chapel, where her midwife, Hilles Whedbee, attempted to alleviate the pain with birth control medication. This treatment was not effective.

15. In or around May 2012, Ms. Payne returned to Hilles Whedbee, who recommended an ablation procedure to treat the pain. An endometrial biopsy performed prior to the ablation procedure, showed complex hyperplasia without atypia.

16. In light of the results of the endometrial biopsy, an ablation procedure was not performed, and Ms. Payne was referred to Dr. David Silverman for consultation.

17. Dr. Silverman recommended a hysterectomy, and strongly encouraged Ms. Payne to agree to a laparoscopic hysterectomy. Dr. Silverman told Ms. Payne that the laparoscopic procedure would allow her to recover faster and would leave a smaller scar than the alternative.

18. Based on Dr. Silverman's counsel, Ms. Payne presented to Sinai Hospital on June 18, 2012, where she underwent a laparoscopic supracervical hysterectomy. This procedure was performed using an Ethicon Morcellex Power Morcellator, which was unbeknownst to Ms. Payne.

19. Prior to this procedure, Dr. Silverman did not communicate all material risks of the procedure that were known to him, including the risk of spreading and seeding malignant and non-malignant tissue, which can lead to painful abnormal and/or recurrent growths within the body. On the day of the procedure, a Sinai Hospital Informed Consent document was provided to Ms. Payne, which not only failed to identify material risks of the procedure, including the risk of spreading and seeding malignant and non-malignant tissue, but also misled Ms. Payne to believe that there were no alternative treatments to the procedure.

20. On June 18, 2012 the laparoscopic hysterectomy by power morcellation was performed.

21. A pathological examination of the tissue removed during the laparoscopic hysterectomy by power morcellation was negative for malignancy but showed proliferative endometrium.

22. Following the procedure using the Power Morcellator, Ms. Payne began suffering from severe chronic and acute pelvic pain associated with her menses.

23. The pain became so severe and debilitating that Ms. Payne went to the emergency room at the Eastern Idaho Regional Medical Center on July 30, 2014.

24. A CT Scan taken revealed a pelvic mass of undetermined significance located near the sigmoid rectal junction.

25. On July 30, 2014, a diagnostic laparoscopy was performed and the pelvic mass was partially resected. The mass could not be completely removed at this time because it was found to be attached the colon.

26. The pathology from the laparoscopy demonstrated that the prior hysterectomy procedure by power morcellation likely caused the fragment to become lodged in the deep pelvis with subsequent adhesion and neovascularization.

27. In or around September 2014, severe pelvic pain again caused Ms. Payne to return to the hospital.

28. On November 4, 2014, Ms. Payne underwent open surgery to resect the remainder of the pelvic mass.

29. Ms. Payne no longer suffers from debilitating pelvic pain, but she has, and will continue to receive, regular monitoring and exams in an attempt to identify any potential recurrence of benign growth in the pelvic region.

B. Background on Laparoscopic Power Morcellators

30. In the United States, over 650,000 women each year will undergo a surgical removal of all or part of the reproductive system and/or fibroids, sometimes including removal of one or both ovaries.

31. In conventional surgeries, the organs remain essentially intact and delivered in that condition from the abdomino-pelvic cavity.

32. In the last few decades, gynecologic surgeons have increasingly performed laparoscopic procedures using a Power Morcellator, like the Morcellex, to remove organs and tissue during abdominal surgeries, including hysterectomies, myomectomies, oophorectomies, and laparotomies.

33. A Power Morcellator is an electrically powered medical device with spinning blades that shred, grind, and core tissue into smaller pieces or fragments inside

the patient so the tissue can be removed through small incisions or extraction "ports" in the abdomen.

34. Power Morcellators are designed with a grasper that pulls the tissue up against the sharp, rotating blades, severing the shredded tissue from the rest of the large mass and continuously pulling cut portions of tissue up through the tube.

35. The Power Morcellator's spinning blade shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery.

36. During tissue morcellation, morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs (such as the loops of the bowel), and cancerous cells can travel to remote areas of the body through the vasculature or lymphatic system.

37. Once disseminated in the body, morcellated fragments can become implanted in surrounding tissue or organs, and begin to grow.

38. When tissue fragments escape into the abdomino-pelvic cavity and seed in other tissue or organs, complications can arise months or years after the surgery.

COUNT I: INFORMED CONSENT – NEGLIGENCE
(David Silverman, LifeBridge Health, Sinai Hospital)

39. Claimant realleges and incorporates by reference as if fully set forth herein the allegations contained in Paragraphs 1 through 38, inclusive.

40. At all times relevant hereto, Dr. Silverman was employed by or was otherwise an actual or apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc.

41. On June 18, 2012, Dr. Silverman performed a supracervical laparoscopic hysterectomy on Claimant using a Morcellex power morcellator.

42. The laparoscopic surgery was performed at Sinai Hospital of Baltimore, Inc.

43. The laparoscopic surgical procedure involved the use of the Power Morcellator to shred, grind, and disseminate benign tissue inside the uterine cavity.

44. Before performing the aforementioned surgery by power morcellation, Dr. Silverman knew or should have known:

a. that the morcellation procedure presented a material risk of disseminating tissue, malignant and non-malignant, throughout the Claimant's body;

b. that the morcellation procedure presented a material risk of causing any disseminated tissue to seed, grow, and/or recur in other parts of the body;

c. that if this benign tissue would spread, seed, recur, and grow in other parts of the body, it would cause abdominal pain and necessitate additional surgical treatment;

d. that the morcellation procedure would result in a more difficult and incomplete pathological diagnosis; and

e. that alternatives existed that would minimize or negate the risk of spreading and seeding malignant and non-malignant tissues in the uterine cavity and throughout Claimant's body.

45. Dr. Silverman owed Claimant a duty to disclose all material risks associated with the surgical procedure prior to performing said procedure, including those material risks stated in the preceding paragraph.

46. Before the aforementioned surgery was performed, Dr. Silverman failed to properly disclose any of the foregoing material risks to Claimant.

47. Before the aforementioned surgery was performed, Dr. Silverman failed to mention, let alone explain, the term "Power Morcellator" to Claimant, nor did Dr. Silverman inform Claimant that he would be cutting, grinding and/or mincing the tissue within the Claimant's body.

48. Before the aforementioned surgery was performed, the only information verbally communicated to Claimant, by Dr. Silverman or any other person, was that the surgery would be laparoscopic, which would enable a faster recovery and a smaller scar.

49. Before the aforementioned surgery, Claimant signed a Sinai "Consent for operation or other procedure," which was supplied to her by Dr. Silverman. The consent form, signed by Dr. Silverman and Claimant, does not disclose any of the material risks stated in Paragraph 44.

50. Furthermore, the consent form provided to Claimant misled the Claimant to believe she had no choice but to under the laparoscopic hysterectomy by power

morcellation. The "Consent for operation or other procedure" stated: "The following alternatives, including no treatment, have been discussed with me. No procedure."

51. Dr. Silverman knew, or in the exercise of reasonable surgical care should have known, that Claimant wanted to know of all material risks associated with the surgical procedure prior to undergoing surgery.

52. Contrary to the accepted standards of medical and surgical care, Dr. Silverman failed to inform Claimant of the potential material risks associated with the surgical procedure.

53. By failing to inform Claimant of the nature and seriousness of the risks stated in Paragraph 44, Dr. Silverman breached his duty to secure the fully informed consent of Claimant prior to commencing the operative procedure.

54. If Claimant would have been aware of the serious risks involved with the laparoscopic surgical procedure using the Power Morcellator, she would not have consented to it.

55. As a result of the unnecessary procedure for which there was not fully informed consent given by Claimant, the Claimant suffered recurrent and chronic pelvic pain which required multiple surgeries to resect the masses caused by the spread of tissue as a result of the use of the Power Morcellator.

56. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are liable for the actions of their agents and/or employees, including Dr. Silverman, pursuant to the doctrines of *respondeat superior* and vicarious liability.

57. As a foreseeable, direct, and proximate result of the aforementioned lack of informed consent by the Health Care Providers, Claimant sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Claimant demands compensatory damages against LifeBridge Health, Inc., Sinai Hospital of Baltimore, Inc., and health care provider David B. Silverman, M.D. for compensatory damages in excess of thirty thousand ($30,000) dollars plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT II: INFORMED CONSENT- NEGLIGENCE – APPARENT AGENCY
(LifeBridge Health, Sinai Hospital)

58. Claimant realleges and incorporates by reference as if fully set forth herein the allegations contained in Paragraphs 1 through 57, inclusive.

59. At all times herein relevant, Dr. Silverman was acting as the apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. with regard to the care and treatment of Claimant. At those times, Claimant was under the reasonable belief that

Dr. Silverman was acting under the control, supervision and/or authority of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. and that each held itself out to the public and to the Claimant in particular as a full service facility capable of providing competent medical care to patients admitted to its facility. Additionally, Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. did not take any affirmative measures to advise Claimant that Dr. Silverman was not acting as an employee, agent and/or representative in connection with the care and treatment of Claimant. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are vicariously liable for the negligence of their apparent agents, servants and employees.

60. As a foreseeable, direct, and proximate result of the aforementioned lack of informed consent by the Health Care Providers, Claimant sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Claimant demands compensatory damages against Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. in excess of thirty thousand ($30,000) dollars plus litigation costs and expenses reasonably incurred;

punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT III: FRAUD- NON DISCLOSURE
(David Silverman, LifeBridge Health, Sinai Hospital)

61. Claimant re-alleges and incorporates by reference as if fully set forth herein the allegations contained in Paragraphs 1 through 60, inclusive.

62. Health Care Providers owed Claimant a duty to fully and accurately disclose all material information and risks regarding the laparoscopic hysterectomy using power morcellation.

63. As Claimant's physician and surgeon, Dr. Silverman owed Claimant a fiduciary duty to disclose all material information related to her health and well-being and any treatment or procedures related thereto.

64. Health Care Providers breached their duties owed to Claimant by failing to disclose the material information and risks associated with the surgical procedure performed on June 18, 2012, by power morcellation, as more fully specified in Paragraph 44 of this complaint.

65. Health Care Providers also breached their duties by misrepresenting to Claimant that her only alternative was to have "no procedure" done.

66. Health Care Providers knew that their omissions were material, and that their representations about the laparoscopic hysterectomy by power morcellation were false, incomplete, misleading, deceptive, and/or deceitful when they were made. Alternatively, Health Care Providers made the representations with such reckless

disregard for the truth that knowledge of the falsity of the representations can be imputed to Health Care Providers.

67. Health Care Providers made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Claimant and with the intention of having Claimant act and rely on them because the laparoscopic procedure require less resources to perform than the safer, more appropriate, total abdominal surgery alternative and/or because a greater financial benefit would be derived from using the Power Morcellator during laparoscopic surgery.

68. Claimant relied with justification on the misrepresentations and omissions by Health Care Providers, which caused Claimant to undergo surgery using the Power Morcellator without knowledge of all material risks.

69. Health Care Providers' actions, and Claimant's justifiable reliance, caused and/or was a substantial contributing factor in causing Claimant to suffer severe injuries and to incur substantial and permanent damages.

70. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are liable for the actions of their agents and/or employees, including Dr. Silverman, pursuant to the doctrines of *respondeat superior* and vicarious liability.

71. As a foreseeable, direct, and proximate result of the aforementioned fraudulent non-disclosure by the Health Care Providers, Claimant sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Claimant demands judgment against the Health Care Providers for compensatory damages in excess of thirty thousand ($30,000) plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT IV: FRAUD- NON DISCLOSURE – APPARENT AGENCY
(LifeBridge Health, Sinai Hospital)

72. Claimant realleges and incorporates by reference as if fully set forth herein the allegations contained in Paragraphs 1 through 71, inclusive.

73. At all times herein relevant, Dr. Silverman was acting as the apparent agent of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. with regard to the care and treatment of Claimant. At those times, Claimant was under the reasonable belief that Dr. Silverman was acting under the control, supervision and/or authority of LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. and that each held itself out to the public and to the Claimant in particular as a full service facility capable of providing competent medical care to patients admitted to its facility. Additionally, Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. did not take any affirmative measures to advise Claimant that Dr. Silverman was not acting as an

employee, agent and/or representative in connection with the care and treatment of Claimant. LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. are vicariously liable for the negligence of their apparent agents, servants and employees.

74. As a foreseeable, direct, and proximate result of the aforementioned fraudulent non-disclosure by the Health Care Providers, Claimant sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

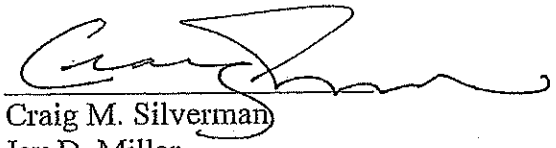
b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of recurrence of cancer, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Claimant demands compensatory damages against Health Care Providers LifeBridge Health, Inc. and Sinai Hospital of Baltimore, Inc. in excess of thirty thousand ($30,000) dollars plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

Dated: December 2, 2015

Respectfully submitted,

LAW OFFICES OF PETER G. ANGELOS, P.C.



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Baltimore, Maryland 21201
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csilverman@lawpga.com

TERI CHAVIS 3549 North Flint Avenue Idaho Falls, Idaho 83401	*	BEFORE THE
	*	HEALTH CARE
Claimant,	*	ALTERNATIVE DISPUTE
v.	*	RESOLUTION OFFICE
LEFEBRIDGE HEALTH, INC. 2401 West Belvedere Avenue Baltimore, Maryland 21215	*	OF MARYLAND
	*	HCADRO No._____
and	*	
SINAI HOSPITAL OF BALTIMORE, INC. 2401 West Belvedere Avenue Baltimore, Maryland 21215	*	
and	*	
DAVID B. SILVERMAN 2435 West Belvedere Avenue, Suite 33 Baltimore, Maryland 21215	*	
Health Care Providers.		

* * * * * * * * * * * * *

ELECTION TO WAIVE ARBITRATION

Pursuant to the authority of § 3-2A-06(b), Courts and Judicial Proceedings Article, Annotated Code of Maryland, the Claimant hereby waives arbitration of the above-captioned matter.

Respectfully submitted,

LAW OFFICES OF PETER G. ANGELOS, P.C.

Craig M. Silverman
Jay D. Miller
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100 N. Charles Street
22nd Floor
Baltimore, Maryland 21201
(410) 649-2000

Circuit Court for Baltimore City
City or County

CIVIL - NON-DOMESTIC CASE INFORMATION REPORT

DIRECTIONS:

Plaintiff: *This Information Report must be completed and attached to the complaint filed with the Clerk of Court unless your case is exempted from the requirement by the Chief Judge of the Court of Appeals pursuant to Rule 2-111(a). A copy must be included for each defendant to be served.*

Defendant: *You must file an Information Report as required by Rule 2-323(h).*

THIS INFORMATION REPORT CANNOT BE ACCEPTED AS AN ANSWER OR RESPONSE.

FORM FILED BY: ☒ PLAINTIFF ☐ DEFENDANT CASE NUMBER _____ (Clerk to insert)

CASE NAME: Teri Chavis (Plaintiff) vs. Johnson & Johnson, et al (Defendant)

JURY DEMAND: ☒ Yes ☐ No Anticipated length of trial: _____ hours or _____ days

RELATED CASE PENDING? ☐ Yes ☒ No If yes, Case #(s), if known: _____

Special Requirements? ☐ Interpreter (Please attach Form CC-DC 41)

☐ ADA accommodation (Please attach Form CC-DC 49)

NATURE OF ACTION (CHECK ONE BOX) / **DAMAGES/RELIEF**

TORTS
- ☐ Motor Tort
- ☐ Premises Liability
- ☐ Assault & Battery
- ☒ Product Liability
- ☐ Professional Malpractice
- ☐ Wrongful Death
- ☐ Business & Commercial
- ☐ Libel & Slander
- ☐ False Arrest/Imprisonment
- ☐ Nuisance
- ☐ Toxic Torts
- ☐ Fraud
- ☐ Malicious Prosecution
- ☐ Lead Paint
- ☐ Asbestos
- ☐ Other _____

LABOR
- ☐ Workers' Comp.
- ☐ Wrongful Discharge
- ☐ EEO
- ☐ Other _____

CONTRACTS
- ☐ Insurance
- ☐ Confessed Judgment
- ☐ Other _____

REAL PROPERTY
- ☐ Judicial Sale
- ☐ Condemnation
- ☐ Landlord Tenant
- ☐ Other _____

OTHER
- ☐ Civil Rights
- ☐ Environmental
- ☐ ADA
- ☐ Other _____

A. TORTS

Actual Damages
- ☐ Under $7,500
- ☐ $7,500 - $50,000
- ☐ $50,000 - $100,000
- ☒ Over $100,000

- ☐ Medical Bills $ _____
- ☐ Property Damages $ _____
- ☐ Wage Loss $ _____

B. CONTRACTS
- ☐ Under $10,000
- ☐ $10,000 - $20,000
- ☐ Over $20,0000

C. NONMONETARY
- ☐ **Declaratory Judgment**
- ☐ **Injunction**
- ☐ **Other** _____

ALTERNATIVE DISPUTE RESOLUTION INFORMATION

Is this case appropriate for referral to an ADR process under Md. Rule 17-101? (Check all that apply)

A. Mediation ☒ Yes ☐ No
B. Arbitration ☐ Yes ☒ No
C. Settlement Conference ☒ Yes ☐ No
D. Neutral Evaluation ☐ Yes ☒ No

TRACK REQUEST

*With the exception of Baltimore County and Baltimore City, please fill in the estimated **LENGTH OF TRIAL**. **THIS CASE WILL THEN BE TRACKED ACCORDINGLY.***

- ☐ 1/2 day of trial or less
- ☐ 1 day of trial time
- ☐ 2 days of trial time
- ☐ 3 days of trial time
- ☐ More than 3 days of trial time

PLEASE SEE PAGE TWO OF THIS FORM FOR INSTRUCTIONS PERTAINING TO THE BUSINESS AND TECHNOLOGY CASE MANAGEMENT PROGRAM AND COMPLEX SCIENCE AND/OR MEDICAL CASE MANAGEMENT PROGRAM (ASTAR), AS WELL AS ADDITIONAL INSTRUCTIONS IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE CITY, PRINCE GEORGE'S COUNTY, OR BALTIMORE COUNTY.

Date _____ Signature _____

BUSINESS AND TECHNOLOGY CASE MANAGEMENT PROGRAM

For all jurisdictions, if Business and Technology track designation under Md. Rule 16-205 is requested, attach a duplicate copy of complaint and check one of the tracks below.

☐ **Expedited**
Trial within 7 months of Filing

☒ **Standard**
Trial within 18 months of Filing

☐ EMERGENCY RELIEF REQUESTED _____ _____
Signature Date

COMPLEX SCIENCE AND/OR MEDICAL CASE MANAGEMENT PROGRAM (ASTAR)

FOR PURPOSES OF POSSIBLE SPECIAL ASSIGNMENT TO AN ASTAR RESOURCE JUDGE under Md. Rule 16-202. Please check the applicable box below and attach a duplicate copy of your complaint.

☐ Expedited - Trial within 7 months of Filing ☒ Standard - Trial within 18 months of Filing

IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE CITY, PRINCE GEORGE'S COUNTY, OR BALTIMORE COUNTY PLEASE FILL OUT THE APPROPRIATE BOX BELOW.

CIRCUIT COURT FOR BALTIMORE CITY (CHECK ONLY ONE)

☐ Expedited	Trial 60 to 120 days from notice. Non-jury matters.
☐ Standard-Short	Trial 210 days.
☒ Standard	Trial 360 days.
☐ Lead Paint	Fill in: Birth Date of youngest plaintiff _____.
☐ Asbestos	Events and deadlines set by individual judge.
☐ Protracted Cases	Complex cases designated by the Administrative Judge.

CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY

To assist the Court in determining the appropriate Track for this case, check one of the boxes below. This information is not an admission and may not be used for any purpose other than Track Assignment.

☐ Liability is conceded.

☐ Liability is not conceded, but is not seriously in dispute.

☐ Liability is seriously in dispute.

CIRCUIT COURT FOR BALTIMORE COUNTY	
☐ Expedited (Trial Date-90 days)	Attachment Before Judgment, Declaratory Judgment (Simple), Administrative Appeals, District Court Appeals and Jury Trial Prayers, Guardianship, Injunction, Mandamus.
☐ Standard (Trial Date-240 days)	Condemnation, Confessed Judgments (Vacated), Contract, Employment Related Cases, Fraud and Misrepresentation, International Tort, Motor Tort, Other Personal Injury, Workers' Compensation Cases.
☐ Extended Standard (Trial Date-345 days)	Asbestos, Lender Liability, Professional Malpractice, Serious Motor Tort or Personal Injury Cases (medical expenses and wage loss of $100,000, expert and out-of-state witnesses (parties), and trial of five or more days), State Insolvency.
☐ Complex (Trial Date-450 days)	Class Actions, Designated Toxic Tort, Major Construction Contracts, Major Product Liabilities, Other Complex Cases.