UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

EDDIE LEE JACKSON, Individually, and as Representative of the Estate of BERNADETTE MCLAUGHLIN JACKSON, Deceased, Plaintiff, v. ETHICON, INC.; ETHICON WOMEN'S HEALTH & UROLOGY DIVISION OF ETHICON, INC.; ETHICON ENDO-SURGERY, INC., JOHNSON & JOHNSON; ABC CORPORATIONS, 1-10; JOHN DOES, 1-10; and JANE DOES, 1-10, Defendants.	)	Case No: 16-cv-3314 JURY TRIAL DEMANDED

PLAINTIFF'S CIVIL ACTION COMPLAINT

Plaintiff EDDIE LEE JACKSON (Mr. Jackson), individually, and as Representative of the Estate of Bernadette McLaughlin-Jackson, deceased, alleges:

PROCEDURAL AND FACTUAL BACKGROUND

I. INTRODUCTION

1. This lawsuit is a personal injury, survivorship and death action against Defendants who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and or selling Johnson & Johnson power morcellators that are medical devices used during laparoscopic uterine surgery.

2. BERNADETTE McLAUGHLIN-JACKSON (Bernadette McLaughlin-Jackson), deceased, underwent a surgical procedure utilizing a Johnson & Johnson power morcellator that caused leiomyosarcoma to spread throughout her body, killing her.

II. PARTIES

3. Plaintiff EDDIE LEE JACKSON (Mr. Jackson) is an adult citizen of the United States of America and a resident of Hoffman Estates, Cook County, Illinois. Mr. Jackson brings suit as an individual entitled to recover damages for the death of his wife Bernadette McLaughlin-Jackson and as representative of the Estate of Bernadette McLaughlin-Jackson. Bernadette McLaughlin-Jackson was at the time of her death an adult citizen of Hoffman Estates, Cook County, Illinois.

4. Defendant JOHNSON & JOHNSON, INC. is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

5. Defendant JOHNSON & JOHNSON SERVICES, INC. is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. Defendant ETHICON, INC. is a New Jersey corporation with its principal place of business at Route 2, West Somerville, New Jersey 08876.

7. Defendant ETHICON ENDO-SURGERY, INC. is an Ohio corporation with its principal place of business at 4545 Creek Road, Blue Ash, Ohio 45242.

8. Defendants, ABC Corporations, 1-10, are fictitious names, corporations, or other similar entities who were engaged in the business of manufacturing, selling, supplying, marketing, or distributing Johnson & Johnson power morcellators, and specifically the morcellator used upon Bernadette McLaughlin-Jackson. Plaintiff does not know the names or capacities, whether corporate, associate or individuals of Defendants sued herein as ABC Corporations, 1-10, inclusive and therefore, Plaintiff sues these Defendants by such fictitious names.

9. Upon information and belief, each of the fictitiously named John Doe Defendants are legally responsible in some manner for the wrongful events and occurrences herein alleged, and each of them was in some manner legally responsible for causing the injuries and damage to Plaintiff as described in this complaint.

10. Plaintiff will seek leave to amend this complaint to allege the true names and capacities of said JOHN DOE Defendants when such information has been ascertained.

11. JOHN DOE Defendants 1-10 are citizens of states other than the State of Illinois.

12. Upon information and belief, Defendants at all relevant times transacted and conducted business in the State of Illinois and these causes of action arise from this activity.

13. Upon information and belief, Defendants at all relevant times committed tortious acts without the State of Illinois causing injury within those States that give rise to these causes of action.

III. VENUE AND JURISDICTION

14. This Court has original jurisdiction pursuant to 28 U.S.C. §1332 because complete diversity exists between Plaintiff, a citizen of the State of Illinois, that is different from the States where the Defendants are incorporated and have their principle places of business, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

15. Venue is proper within this District under 28 U.S.C. §1391 and it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391 (a) and (c).

IV. BACKGROUND AND FACTS

A. PLAINTIFF'S SURGERY AND RESULTANT SPREAD OF LEIOMYOSARCOMA

16. On April 17, 2008 Bernadette McLaughlin-Jackson underwent a laparoscopic surgical procedure known as supracervical hysterectomy with morcellation of the uterus performed by Humberto Lamoutte, M.D. and Raja Chatterji, M.D. at Advocate Sherman Hospital, Elgin, Illinois, for removal of uterine fibroids. A Johnson & Johnson power morcellator was used.

17. May 5, 2011 Bernadette McLaughlin-Jackson was diagnosed with abdominal leiomyosarcoma, the cancer spread, and as result she died May 30, 2011. She was 42 years old.

18. Prior to the April 17, 2008 morcellation procedure, Bernadette McLaughlin-Jackson had no medical evidence that she had leiomyosarcoma.

19. Prior to her surgery, Bernadette McLaughlin-Jackson was not warned that the Johnson & Johnson power morcellator was a cause of the spread of leiomyosarcoma.

B. BACKGROUND ON JOHNSON & JOHNSON POWER MORCELLATORS

20. In the United States, it is estimated that 650,000 women a year will undergo a surgical myomectomy or hysterectomy for the management of symptomatic uterine fibroids.

21. In conventional non-Power morcellator hysterectomies, the women's entire uterus is removed essentially intact and in conventional myomectomies the uterine fibroids are removed essentially intact and the women's uterus is left intact.

22. In the last few decades, laparoscopic procedures with electric laparoscopic power morcellators used to remove uterine fibroids or other tissue have increasingly replaced traditional open abdominal surgical hysterectomies, myomectomies, and laparotomies.

23. Laparoscopic power morcellators are electrically powered medical tools with spinning blades that shred, grind, and core tissue into smaller pieces or fragments so the tissue can be removed through small incisions in the abdomen.

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

25. The morcellator's spinning blade shreds tissue at a high speed, dispersing cellular particles throughout the abdomen.

26. During tissue morcellation, morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs, and tissue cells can travel to remote areas of the body through the vasculature or lymphatic system. These escaped fragments can become implanted in surrounding tissue or organs, begin to grow, and result in complications months or years after surgery.

27. Defendants were responsible for designing, researching, developing, packaging, labeling, marketing, promoting, distributing, or selling laparoscopic power morcellators under at least the following trade names: the Gynecare Morcellex, Tissue Morcellator, and Morcellex Sigma Tissue Morcellator System.

C. THE LAPAROSCOPIC POWER MORCELLATOR USED IN BERNADETTE MCLAUGHLIN-JACKSON'S SURGERY WAS DEFECTIVE IN DESIGN AND RESULTED IN AN AVOIDABLE RISK OF HARM, CAUSING BERNADETTE MCLAUGHLIN-JACKSON INJURY AND DEATH.

28. Long before Bernadette McLaughlin-Jackson's 2008 surgery, Defendants knew or should have known their laparoscopic power morcellators could spread occult malignant tissue fragments, resulting in injury and death.

29. Although evidence was available to Defendants for years prior to Bernadette McLaughlin-Jackson's surgery, Defendants failed to respond to multiple published studies and reports describing the risk of spreading

parasitic uterine myomas with morcellator use, and failed to design their laparoscopic power morcellators to reduce this risk.

30. Upon information and belief, Defendants monitor the medical and lay media for articles on issues concerning their products.

31. Upon information and belief, all or substantially all of the literature cited below was known by Defendants at or before publication, and certainly should have been known by Defendants.

32. Defendants knew or should have known that their laparoscopic power morcellators could spread occult malignant tissue fragments, resulting in injury and death. Information that was known or should have been known by Defendants included, but was not limited to:

a. August 6, 1991, a patent for a Surgical Tissue Bag and Method for Percutaneously Debulking Tissue that describes the potential for laparoscopic power morcellators to spread and implant malignant tissue fragments in the body.

b. The patent reads:

> 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. Those invasive open cavity procedures increase the recovery period of the patient and subject the patient to additional discomfort and complications.
> As a result, the debulking of large malignant tissue volume percutaneously through an access sheath presents significant morbidity risks to the patient.

c. The patent summary of the invention further reads "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 publicly available before Defendants first sought approval of their laparoscopic power morcellators. Defendants knew or should have known its content.

e. Prominent medical journals reporting on laparoscopic power morcellators and the risk of spreading undetected cancer also began to accumulate in the 1990s, and reporting has continued.

f. 1997 Schneider published a case report in THE AMERICAN JOURNAL OF OBSTETRICS AND GENECOLOGY titled "Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation." It discussed a patient who underwent morcellation surgery, and died the next year from rapid progression of uterine adenocarcinoma undetected prior to surgery. The author wrote 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." J. AM. OBSTET, GYNECOL., 177(1):478-9(1997).

g. 1998 Hutchins and Reinoehl published a case report writing "[b]ecause of the large quantity of tissue of such a uterus, it would be anticipated that numerous fragments would be generated during morcellation." The authors, further, wrote the morcellated fragments could become concealed in surrounding organs making it difficult for the

surgeon to identify and remove them all. J. AM ASSOC. GYNECOL. LAPAROSC., 5(3):293—295 (1998).

h. 2005 LaCoursiere et al. published a case report, writing "[t]he use of a power morcellator may produce smaller fragments than other techniques." The authors wrote "implantation, rather than resorption of residual fragments of cervix and myometrium can occur," having "implications for possible benign and malignant sequelae." LaCoursiere et al., "Retained fragments after total laparoscopic hysterectomy, J. MINIM. INVAS. GYNECOL. 12:67-69 (2005).

i. 2010 Larrain et al. published, writing "[i]f retained fragments can establish a blood supply and grow with benign disease, it is of concern that in situations in which an unsuspected malignant lesion is inadvertently morcellated, aberrant fragments will grow and metastasize." Larrain et al., "Iatrogenic Parasitic Myomas: Unusual Late Complications of Laparoscopic Morcellation Procedures," MINIM. INVAS. GYNECOL., 17:719-724, 722 (2010).

j. This evidences Defendants notice that their laparoscopic power morcellators exposed patients to risk of injury and death.

33. Defendants knew or should have known that, for women undergoing laparoscopic hysterectomies or myomectomies for presumed fibroids, the risk of having a hidden deadly sarcoma was much higher than 1 in 10,000.

a. 1990 Leibsohn et al. published, writing ". . . women with signs and symptoms of uterine leiomyomas that warrant hysterectomy

have about a 1 in 40 chance of having a uterine leiomyoscarcoma." Leibsohn et al., "Leiomyoscarcoma in a series of hysterectomies performed for presumed uterine leiomyomas," AM. J. OBSTET. GYNECOL., 162:968-76 (1990).

b. 1999 Takamizawa et al. published, writing that in their study 2 out of 923 women who underwent hysterectomies for presumed benign fibroids had undiagnosable hidden sarcomas before their hysterectomies. The authors wrote this was consistent with other studies suggesting 2 to 5 patients in 1,000 who undergo surgery for presumed fibroids have uterine sarcomas. Takamizawa et al., "Risk of Complications and Uterine Malignancies in Women Undergoing Hysterectomy for Presumed Benign Leiomyomas": GYNECOL. OBSTET. INVEST., 48:193-196 (1999).

c. These publication were available to Defendants when or before published, and were or should have been known to Defendants. Yet, upon information and belief, defendants sought approval for their laparoscopic power morcellators, representing a risk of 1 in 10,000, and continued this representation in marketing their morcellators.

34. Defendants knew or should have known that adequate screening for malignancy prior to undergoing laparoscopic power morcellation surgery was difficult or impossible.

a. 1990 Leibsohn et al. described difficulties in diagnosing leiomyoscarcoma preoperatively. They wrote, "abdominal ultrasonography of the pelvis and cervical cytology are not helpful

preoperative tests for the diagnosis [of] leiomyoscarcoma of the uterus" AM. J. OBSTET. GYNECOL., 162:968-76 (1990).

b. 2001 Stewart published, explaining that malignant leiomyoscarcoma and benign fibroids may share histological features. This increases the clinicians' difficulty in identifying malignant potential of smooth muscle uterine tumors." Stewart, "Uterine Fibroids, THE LANCET, 357:293-98 (2001)

c. 2008 Bansel et al. published, writing that the predictive value of endometrial biopsy or curettage for diagnosing uterine sarcoma was inadequate. They urged the need for novel diagnostic techniques. Bansel et al., "The utility of preoperative endometrial sampling for the detection of uterine sarcoma," GYNECOL. ONCOL., 110:43-48 (2008).

d. 2010 Della Badia and Karini published a case report warning that reliable methods for preoperative diagnosis of endometrial sarcoma were non-existent. They wrote that when malignancy is diagnosed prior to surgery, the standard of care requires total hysterectomy, not morcellation. Della Badia and Karini, "Endometrial stromal sarcoma diagnosed after uterine morcellation in laparoscopic supracervical hysterectomy," J. MINIM. INVAS. GYNECOL.," J. Minim. Invas. Gynecol., 17:791-93 (2010)

35. Defendants knew or should have known that women undergoing surgery with laparoscopic power morcellation suffered worse long-term surgical outcomes than women undergoing other available treatment options, because of the cancer risks associated with the use of morcellation.

a. 2002 Goto et al. published a study and wrote:

> Leiomyosarcoma of the uterus is one of the most difficult neoplasms to cure in gynecologic oncology. Its malignant behaviors such as rapid growth and high rate of metastasis are notorious.
>
> The 5-year survival in patients with advance stages (stage III or higher) is less than 10% although leiomyoscarcoma resembles leiomyoma in clinical feature. Until now LMS was diagnosed only in advanced stages or accidentally at to total abdominal hysterectomy. . .
>
> Therefore it seems that the effective treatment of LMS is surgical removal of the tumor in the earlier stages. The problem regarding treatment of LMS is the difficult preoperative differential diagnosis of LMS in the early stages from leiomyoma, which is the most common tumor of the uterus.

Goto et al., "Usefulness of Gd-DTPA contrast-enhanced dynamic MRI and serum determination of LDH and its isozymes in the differential diagnosis of leiomyoscarcoma for degenerated leiomyoma of the uterus." INT. J. GYNECOL. CANCER, 12:354-61 (2002).

b. 2003 Morice et al. published, writing that they found a substantial increase in pelvic recurrence of uterine sarcoma at 3 months in 34 patients who had morcellation during their initial surgery compared with 89 patients without morcellation. They wrote that, when a uterine sarcoma diagnosis is made preoperatively, the optimal treatment is total abdominal hysterectomy and bilateral salpingo-oophorectomy without morcellation. Morice et al, "Prognostic value of initial surgical procedure for patients with uterine sarcoma: analysis of 123 patients," EUR. J. GYNAECOL. ONCOL., 24(3-4):237-40, 238-39 (2003).

c. 2008 Einstein et al. published a prospective study, reporting that 40% of the study patients undergoing morcellation developed

upstaged cancer compared with only 8% who had a supracervical hysterectomy. They wrote that this supported a trend toward worse outcomes in patients with morcellation. 2008 Einstein et al., INT. J. GYNECOL CANCER, 18:1065-70 (2008)

d. 2009 Perri et al. published and wrote:

> [U]nfortunately, however, it is not unusual to diagnose LMS only postoperatively because its symptoms and signs resemble those of benign leiomyomas (LMs), and there are no imaging techniques for differentiation between the two. Consequently, on the assumption that they have LM, some patients with LMS are treated initially with hysteroscopic or abdominal myomectomy, subtotal hysterectomy, or laparoscopic hysterectomy or myomectomy with a morcellator knife. Those surgical techniques, unlike total abdominal hysterectomy (TAH), are likely to involve tumor injury or cut-through.

The authors wrote that their data evidenced significant disadvantage for patients whose primary surgery involved tumor cut-through. Perri et al., "Uterine leiomyosarcoma: Does the primary surgical procedure matter?" INT. J. GYNECOL. CANCER, 19(2):257-260 (2009).

e. 2010 Larrain et al. wrote that if malignancy is suspected or known, morcellation is "formally proscribed." MINIM. INVAS. GYNECOL., 17:719-724, 722 (2010).

f. 2011 Park et al. published and wrote that women undergoing morcellation suffered worse outcomes than women who were not morcellated. They reported a statistically significant difference in 5 year disease free survival rates between non-morcellated patients (85%) and morcellation patients (55%). And they reported a statistically significant difference in 5 year abdominal-pelvic disease-free survival between non-

morcellated patients (89%) and morcellated patients (58%). They wrote that iatrogenic rupture and intraperitoneal spillage of tumor may adversely affect outcomes of patients with apparently early low-grade endometrial stromal sarcoma. For these patients the only establish curative treatment was complete surgical excision. Park et al., "The impact of tumor morcellation during surgery on the outcomes of patients with apparently early low-grade endometrial stromal sarcoma of uterus," ANN. SURG. ONCOL., 18:3452-61 (2011)

36. Defendants knew or should have known that when malignant tissue undergoes laparoscopic power morcellation, the resultant tissue specimens can delay diagnosis because their condition can prevent the pathologist from properly identifying and staging cancer. This can worsen a patient's prognosis and treatment outcome.

a. 2005 Reka et al. published a case report and wrote, ". . . one of the disadvantages of tissue morcellation is loss of the gross appearance of the specimen and the possibility of missing the most suspicious area for the microscopic evaluation." Reka et al., "Unexpected complications of uterine myoma morcellation," AUST. N.Z. J. OBSTET. GYNECOL., 45:248-49 (2005)

b. 2011 Hagemann et al. published a case series and discussed problems analyzing morcellated specimens. They wrote that there is little evidence to guide pathology examinations of morcellated specimens that are fragmented and unoriented. Hagemann et al., "Risk of Occult

malignancy in morcellated hysterectomy: a case series," INT. J. GYNECOL. CANCER, 30:478-83 (2011)

37. The many publications placed Defendants on notice that their laparoscopic power morcellators were associated with and could cause the spread of parasitic uterine myomas. But the laparoscopic power morcellator used on Bernadette McLaughlin-Jackson was, as designed, manufactured and marketed, unsafe for its intended purpose and defective in design. Bernadette McLaughlin-Jackson, therefore was subjected to avoidable risk of harm, including injury and death.

38. Defendants should have designed, marketed and sold their laparoscopic power morcellators with a containment bag or system specifically designed to minimize or prevent the risk of spreading tissue. Upon information and belief, such a 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. The failure to design, develop, manufacture, market and sell the morcellator with a containment bag or system was negligent and fell below the standard of care expected of a reasonable medical device manufacturer.

39. And, at the time of Bernadette McLaughlin-Jackson's surgery, numerous other treatment options for fibroids were available. These options had established safety profiles and posed lower risks. They included, but were not limited to, total abdominal hysterectomies, minimally-invasive hysterectomies and myomectomies.

40. The laparoscopic power morcellator used on Bernadette McLaughlin-Jackson was defectively designed, proximately causing injury and death.

C. THE LAPAROSCOPIC POWER MORCELLATOR USED IN BERNADETTE MCLAUGHLIN-JACKSON'S SURGERY CONTAINED AN INADEQUATE WARNING

41. Defendants failed to provide an adequate warning about the true risks of spreading parasitic uterine myomas from the use of their laparoscopic power morcellators.

42. 1995 a power morcellator was first marketed based on published data from 11 patients.

43. Power morcellators are Class II medical devices as regulated by the Food and Drug Administration (FDA) Center for Medical Devices and Radiological Health. The device required only a 510(k) approval. Each time Defendants sought FDA approval for marketing a new power morcellator, Defendants needed only assert the new device was substantially similar to a previously marketed device. Pre-market approval was not required.

44. When the laparoscopic power morcellator used in Bernadette McLaughlin-Jackson's surgery cleared FDA, Defendants were obligated to ensure the quality and safety of this product. Defendants have a continuing duty of medical device surveillance and vigilance and a duty to inform surgeons, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned about their marketed products.

45. FDA guidance to medical device manufacturers requires inclusion of an appropriate warning when there is reasonable evidence of an association

of a serious hazard with the use of the device. A causal relationship is not required to trigger an appropriate warning. *See* Device Labeling Guidance #G91-1-blue book memo, March 8, 1991.

46. Defendants ignored evidence about uterine myoma risks, and exposed Bernadette McLaughlin-Jackson to avoidable injury and death by failing to disclose:

a. The difficulty of effectively diagnosing uterine cancer prior to or during surgery;

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

c. The actual rates at which laparoscopic power morcellators spread parasitic uterine myomas;

d. Laparoscopic power morcellators are associated with worse long-term medical outcomes than other fibroid treatments because of the risk of parasitic uterine myomas being spread and implanted by the use of the device; and

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

47. Upon information and belief, at the time of Bernadette McLaughlin-Jackson's surgery, the Defendants' instructions for use that accompanied their laparoscopic power morcellator contained a caution that 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."

48. The device used on Bernadette McLaughlin-Jackson failed to adequately warn of the potential of the laparoscopic power morcellator to spread parasitic uterine myomas.

49. The laparoscopic power morcellator used on Bernadette McLaughlin-Jackson failed to contain a recommendation to use a tissue extraction bag to minimize the risk of spreading parasitic uterine myomas.

50. A statement about use of a tissue extraction bag only when cancer is detected and suspected did not and could not eliminate the risk of dissemination and spreading of parasitic uterine myomas. Such a statement ensured harm to patients by providing a false and inadequate warning.

51. Neither the 510(k) submissions, nor Defendants' inadequate warnings concerning their laparoscopic power morcellators, adequately instructed Bernadette McLaughlin-Jackson or her surgeon that an appropriate tissue bag to contain shredded tissue fragments should be used to prevent or minimize the risk of disseminating and spreading parasitic uterine myomas.

52. Defendants' also failed to adequately warn of the risks associated with their laparoscopic power morcellators including but not limited to:

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

b. The failure to adequately warn because the warnings contained no information about the risk of disseminating and spreading parasitic uterine myomas;

c. The failure to timely include a Black Box Warning regarding the risks of disseminating and spreading parasitic uterine myomas; and

e. The failure to timely include a Contraindication regarding the risks of disseminating and spreading parasitic uterine myomas.

D. FDA ACTION AND THE WORLD WIDE WITHDRAWAL OF JOHNSON & JOHNSON LAPAROSCOPIC POWER MORCELLATORS IN 2014.

53. On April 17, 2014, 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.

54. 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 leiomyoscarcoma. If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma there is 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.*

55. FDA listed in "Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids" the studies it relied on in reaching its conclusions on the prevalence of unsuspected uterine sarcoma and uterine leiomyoscarcoma. The studies were published in highly regarded medical journals, ranging in publication dates from 1980 to 2014.

56. Shortly after 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 laparoscopic power morcellator could unintentionally spread. The publication data supports a 1 in 368 risk of occult malignancy that is consistent with FDA's report of a 1 in 352 risk of unsuspected uterine sarcoma.

57. July 10-11, 2014 FDA convened an Advisory Committee meeting on laparoscopic power morcellation. Resulting recommendations included:

a. Laparoscopic 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.

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.*

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.*

58. April 30, 2014, Johnson & Johnson suspended worldwide sale of laparoscopic power morcellators.

59. July 30, 2014, Johnson & Johnson issued an urgent worldwide withdrawal of Ethicon morcellators.

60. November 24, 2014, FDA issued an updated FDA Safety Communication regarding Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy. FDA issued Immediately In Effect guidance, asking all manufacturers of laparoscopic power morcellators to include 2 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 recommended doctors share this information with their patients.

EQUITABLE TOLLING OF APLICABLE STATUTES OF LIMITATION

61. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including discovery rule and fraudulent concealment.

62. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the plaintiff knew, or through the exercise of reasonable care and diligence should have known of facts indicating that Decedent had been injured, the cause of action and the tortious nature of the wrongdoing that caused the injury.

63. Despite diligent investigation, the cause of Bernadette McLaughlin-Jackson's injury and death, the nature of her injury and death and damages, and their relationship to laparoscopic power morcellation was not discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

64. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the truth, quality and nature of Bernadette McLaughlin-Jackson's injuries and death and the connection between the injuries and death and Defendants' tortious conduct. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, Bernadette McLaughlin-Jackson, and Bernadette McLaughlin-Jackson's prescribing physicians and her healthcare facilities the true risks associated with laparoscopic power morcellation.

65. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with laparoscopic power morcellation as this was non-public information over which Defendants had and continue to have exclusive control and because Defendants knew that this information was not available to Plaintiff, Bernadette McLaughlin Jackson, Bernadette McLaughlin-Jackson's medical providers and to her health facilities. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of facts.

66. Plaintiff and Bernadette McLaughlin-Jackson had no knowledge that Defendants were engaged in the wrong doing alleged in this complaint. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

COUNTS

COUNT 1 – NEGLIGENCE

67. The paragraphs above are incorporated by reference hereto as if fully set forth at length.

68. Defendants owed a duty to design, manufacture, label, market, distribute, supply and/or sell Johnson & Johnson power morcellators in such a way as to avoid harm to persons upon whom they were used, such as Bernadette McLaughlin-Jackson, or to refrain from such activities following knowledge and/or constructive knowledge that the products were harmful to persons upon whom they are used.

69. Defendants owed a duty to adequately warn of the hazards and dangers associated with the use of Johnson & Johnson power morcellators used on patients such as Bernadette McLaughlin-Jackson.

70. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees were guilty of carelessness, recklessness, negligence, gross negligence and 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, Johnson & Johnson power morcellators as described in this complaint, and including but not limited to:

a. failing to conduct adequate and appropriate testing;

b. failing to recognize the risks of harm associated with Johnson & Johnson power morcellators;

c. failing to respond promptly and appropriately to their own testing and studies performed by others, and available scientific and medical information reporting risks of injury and death;

d. failing to recommend testing and monitoring of patients upon whom such devices were used;

e. failing to monitor the post-market performance of such devices and the adverse events associated with such devices;

f. concealing from the FDA, National Institutes of Health, the general medical community and patients, their full knowledge and experience regarding the risks associated with such devices;

g. promoting, marketing, advertising or selling Johnson & Johnson power morcellators given their knowledge and experience associated with such devices;

h. failing to withdraw Johnson & Johnson power morcellators from the market, restrict the use of such devices, or warn of the risks associated with these devices;

i. failing to fulfill the standard of care required of a reasonable, and prudent, designer, manufacturer, and seller of medical devices;

j. placing and/or permitting the placement of Johnson & Johnson power morcellators, into the stream of commerce without adequately warning of the risks associated with such devices;

k. failing to disclose to the medical community facts relating to the risks associated with Johnson & Johnson power morcellators;

l. promoting Johnson & Johnson power morcellators as safe or safer than other alternative treatment options;

m. promoting Johnson & Johnson power morcellators on websites for the purpose of creating user and consumer demand;

n. failing to appropriately design these devices;

o. failure to appropriately warn of the risks of these devices; and

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

71. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff and Bernadette McLaughlin-Jackson suffered serious injuries, death, and/or financial losses and harm.

WHEREFORE, Eddie Lee Jackson, Individually and as Representative of the Estate of Decedent, Bernadette McLaughlin-Jackson, respectfully requests that this court enter judgment in his favor and against Defendants in an amount in excess of $75,000.00, plus interest, costs, punitive damages, and attorney's fees.

COUNT II – STRICT LIABILITY

72. The paragraphs above are incorporated by reference.

73. As a result of the unreasonably dangerous and defective condition of the Johnson & Johnson power morcellators that Defendants manufactured, designed, labeled, marketed, distributed, supplied or sold, or placed into the stream of commerce, they are strictly liable to the Plaintiff and Bernadette McLaughlin-Jackson for their injuries and losses, specifically including Bernadette McLaughlin-Jackson's death, that they directly and proximately caused, based on the following:

a. failing to properly and adequately design Johnson & Johnson power morcellators;

b. failing to properly and adequately manufacturer Johnson & Johnson power morcellators; and,

c. failing to properly market Johnson & Johnson power morcellators.

74. In addition, the occurrence and Plaintiff's and Bernadette McLaughlin-Jackson's injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying or selling or placing into the stream of commerce the Johnson & Johnson power morcellators without proper and adequate warnings regarding the risks associated with the devices.

WHEREFORE, Plaintiff Eddie Lee Jackson, Individually and as Representative of the Estate of Decedent, Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT III – BREACH OF EXPRESS WARRANTY

75. The paragraphs above are incorporated by reference.

76. In marketing Johnson & Johnson power morcellators, Defendants warranted that such devices safe for intended use.

77. Defendants breached its warranty as such devices were unsafe. They were associated with a significant and undisclosed risks of injury and death.

78. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and/or Bernadette McLaughlin-Jackson suffered serious injuries, including death, or financial losses.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor and against Defendants.

COUNT IV – BREACH OF IMPLIED WARRANTY

79. The paragraphs above are incorporated by reference.

80. At all relevant and material times, Defendants designed, manufactured, distributed, marketed, advertised, promoted, and sold Johnson & Johnson power morcellators.

81. At all relevant times, Defendants intended that Johnson & Johnson power morcellators be used just as Bernadette McLaughlin-Jackson's physicians and hospital did when she underwent surgery. Defendants impliedly warranted such devices to be of merchantable quality, safe and fit for such use, and adequately tested.

82. Defendants breached these implied warranties as follows:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentation, publications, notice letters, and regulatory submissions that Johnson & Johnson power morcellators were safe, but failed to disclose and concealed information about the substantial risks of serious injury and/or death associated with these devices.

b. Defendant represented that Johnson & Johnson power morcellators were as safe as or safer than other alternative treatment options, but failed to disclose and concealed information about the

substantial risks of serious injury and death associated with these devices; and,

c. Defendants represented that Johnson & Johnson power morcellators were more efficacious than other alternative treatment options, but failed to disclose and concealed information about the actual efficacy of such devices.

83. In reliance upon Defendants' implied warranty, Bernadette McLaughlin-Jackson's physicians and hospital used these devices as Defendants intended, recommended, promoted, instructed, and marketed.

84. Defendants breached their implied warranty, because the devices were not of merchantable quality, safe and fit for their intended use, or adequately tested.

85. As a direct and proximate consequence of Defendants' breach of implied warranty, intentional acts, omissions, misrepresentations and other wrongful acts and omissions described in this complaint, the Plaintiff and Bernadette McLaughlin-Jackson sustained injuries and damages alleged herein including pain and suffering and mental anguish.

86. As a further direct and proximate result of the acts of Defendants, Plaintiff suffered emotional distress and loss of consortium.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor, and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT V – CAUSE OF ACTION ON BEHALF OF PLAINTIFF (FRAUDULENT MISREPRESENTATION)

87. The paragraphs above are incorporated by reference.

88. Defendants, having undertaken the design, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation owed a duty to provide accurate and complete information regarding said devices.

89. Prior to Bernadette McLaughlin-Jackson undergoing her surgery, Defendants fraudulently misrepresented, that the use of their device for uterine morcellation was safe and effective.

90. Defendants had a duty to provide Bernadette McLaughlin-Jackson's physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

91. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Bernadette McLaughlin-Jackson, and the medical community to act in reliance by purchasing and using the uterine morcellator sold by Defendants.

92. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of Plaintiffs' injuries.

93. As a direct and proximate result of the fraud of Defendants, Plaintiff and Bernadette McLaughlin-Jackson suffered serious personal physical injury, death, pain and suffering and severe mental and emotional distress and economic loss and harm.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor, and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT VI - VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICE ACT

94. The paragraphs above are incorporated by reference.

95. At all times relevant, the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 et seq., (hereinafter "ICFA") prohibits "the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omissions of any material fact … in the conduct or any trade of commerce" and declares such acts or practices as unlawful.

96. By engaging in the conduct described above, the Defendants have violated the ICFA by, among other things:

a. Engaging in unfair or deceptive trade practices as defined in the statute by making false and misleading oral and written statements that had, and have the capacity, tendency, or effect of deceiving or misleading consumers;

b. Engaging in unfair or deceptive trade practices as defined in the statute by failing to state material facts, the omission of which deceived or tended to deceive – both the public generally, and Plaintiff, specifically – including, but not limited to, facts relating to the health consequences of the use of the Johnson & Johnson power morcellators; and

c. Engaging in unfair or deceptive trade as defined in the statute by promoting the Johnson & Johnson power morcellators as safe and effective by knowingly and falsely representing that their laparoscopic power morcellators were fit to be used for the purpose for which they were intended, when in fact said devices were defective and dangerous

97. As a direct and proximate result of the Defendants' conduct in violation of the ICFA, Plaintiff and Bernadette McLaughlin-Jackson suffered injuries and economic loss. Had Defendants not engaged in the deceptive conduct described herein, Bernadette McLaughlin-Jackson would not permitted or paid for laparoscopic power morcellation that was used on her during her surgery (directly, or through her surgeon, and/or health care facility at which her surgery was performed), and would not have incurred related medical costs and injury.

98. At all material times, the Defendants actually knew of the defective nature of laparoscopic power morcellator as set forth herein, and blatantly continued to make false and/or misleading promotions, advertising, representations, and statements regarding the laparoscopic power morcellator so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want to care as to establish that their actions were a result of fraud, actual malice and the conclusions and deliberate disregard of foreseeable harm to Bernadette McLaughlin-Jackson, thereby entitling Plaintiff to punitive damages. At all material time, Defendants used and employed the above stated unfair and deceptive methods, acts, and practices willfully and knowingly in violation of the IFCA and that Plaintiff is therefore entitled to damages.

99. As a direct and proximate result of the defective and unreasonably dangerous condition of the laparoscopic power morcellator, Plaintiff and

Bernadette McLaughlin-Jackson suffered severe personal injury, death, pain and suffering and severe emotional distress and economic loss and harm.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor, and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT VII – EDDIE LEE JACKSON – LOSS OF CONSORTIUM

100. Plaintiffs repeat, reiterate and reallege each and every allegation of the Complaint with the same force and effects as if more fully set forth herein.

101. Eddie Lee Jackson was legally married, and as such, is entitled to damages for the loss of love, enjoyment, society and services of his wife, Bernadette McLaughlin-Jackson.

102. As a direct and proximate result of the foregoing, Plaintiff, Eddie Lee Jackson, was deprived of the love and enjoyment of the services and society of his spouse, Bernadette McLaughlin-Jackson, and has suffered and will continue to suffer emotional damages and economic loss, and have otherwise been emotionally and economically injured.

103. That Eddie Lee Jackson's injuries and damages are permanent and will continue into the future for his life time.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor, and against Defendants in an

amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT VII – WRONGFUL DEATH

104. The paragraphs above are incorporated by reference.

105. Plaintiff brings this cause of action to recover for the wrongful death of Bernadette McLaughlin-Jackson which includes loss of society, service, love affection and companionship sustained by the next-of-kin as a result of Bernadette McLaughlin-Jackson's death, and funeral expenses and costs of administration and attorney fees. Bernadette McLaughlin-Jackson's heirs and next-of-kin suffered pecuniary losses and the loss of society, support, compassion, affection, and companionship as a result of Bernadette McLaughlin-Jackson's wrongful death.

106. Plaintiff claims damages for all administrator's expenses suffered by reason of the death of Decedent, including, but not limited to medical, hospital, funeral and burial expenses and expenses of estate administration and other expenses recoverable under the Wrongful Death Act.

107. Plaintiff claims damages for loss of the monetary support that Decedent, Bernadette McLaughlin-Jackson, would have provided to beneficiaries during her lifetime, including, but not limited to, earnings, maintenance, support, and other similar losses recognized under the Wrongful Death Act that they would have received from her for the rest of her natural life.

108. Plaintiff claims damages, under the Wrongful Death Act, for all pecuniary losses suffered by the beneficiaries.

109. Plaintiff claims damages, under the Wrongful Death Act, in an amount to compensate beneficiaries for the losses of contribution between the time of death and today, and the amount of support that Decedent would have contributed to them in the future.

110. Plaintiff claims damages, under the Wrongful Death Act, for services provided or which could have been expected to have been provided in the future by Decedent, as well as household services.

111. Plaintiff claims damages, under the Wrongful Death Act, for loss of guidance, tutelage and other similar losses recognized under the Wrongful Death Act that would have been provided to the beneficiaries.

112. Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, claims damages, under the Wrongful Death Act, for his past and future loss of support from the reasonably expected earning capacity of the Decedent; loss of services of the Decedent, loss of the society of the Decedent, including care, assistance, attention, protection, advice, guidance, counsel, instruction, training and education suffered by the Dependent children, loss of prospective inheritance of the Decedent's heirs at law at the time of the Decedent's death; mental anguish, and reasonable funeral or burial expenses incurred as a result of the wrongful death and other similar losses recognized under the Wrongful Death Act.

113. Plaintiff claims, under the Wrongful Death Act, the full measure of damages allowed under the law and under the categories of administrator's

expenses, support and services as defined under the laws of the State of Illinois.

WHEREFORE, Plaintiff, Eddie Lee Jackson, Individually and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this Court enter judgment in his favor and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT IX – SURVIVAL ACTION

114. The paragraphs above are incorporated by reference hereto as if set forth at length.

115. Plaintiff brings this Survival Action on behalf of the Estate of Decedent, Bernadette McLaughlin-Jackson, as representative of that Estate, for pain, suffering due to the physical injuries and emotional damages and suffering knowing that she was going to die. Bernadette McLaughlin-Jackson expended, became indebted and liable for medical and hospital expenses all due to Defendant's misconduct.

116. As a result of the death of Decedent, her Estate has been deprived of the economic value of her life expectancy and Plaintiff, Eddie Lee Jackson, as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully, claims under the Survival Act, damages for all pecuniary losses suffered by the Estate of Bernadette McLaughlin-Jackson as a result of her death, including all loss of income, earnings, retirement income and benefits and Social Security income, until death, as a result of said Decedent's death.

117. Plaintiff further claims under the Survival Act the total amount that Decedent would have earned between today and the end of her life expectancy; Plaintiff especially seeks the total amount of future lost earning capacity, including, but not limited to the total amount of future lost earnings and earning capacity, including, but not limited to the total lost future net earnings for Decedent, less her cost of personal maintenance.

118. Plaintiff further claims under the Survival Act, damages for embarrassment, humiliation, and mental anguish.

119. Plaintiff further claims under the Survival Act damages for the conscious pain and suffering, and inconvenience endured by Decedent prior to her death, including, but not limited to physical pain and suffering, mental pain and suffering, and the fright and mental suffering attributed to the peril leading to Decedent's death.

120. Plaintiff claims the full measure of damages under the Survival Act and decisional law interpreting said Act.

WHEREFORE, Plaintiff Eddie Lee Jackson, Individually, and as Representative of the Estate of Bernadette McLaughlin-Jackson, respectfully requests this court enter judgment in his favor and against Defendants in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

Respectfully submitted,

/s/ Michael T. Gill

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