UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS
HOT SPRINGS DIVISION

15-6100

LARRY DON POWELL, Individually and as the Representative of the Estate of KIMBERLY POWELL, DECEASED,

Plaintiff,

v.

ETHICON, INC., a corporation d/b/a/ ETHICON WOMEN'S HEALTH & UROLOGY; and JOHNSON & JOHNSON, a corporation,

Defendants.

JURY DEMAND

COMPLAINT

This action for money damages is brought by Larry Don Powell, individually and as the personal representative of the Estate of Kimberly Powell, deceased. It is a an action for wrongful death and other losses against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology ("Ethicon"), and Johnson & Johnson (J&J), which owns Ethicon, caused by said Defendants' morcellator device, as set forth below.

Jurisdiction and Venue

1. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different states.

2. Venue in this Court is proper under 28 U.S.C. § 1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

Parties

3. Plaintiff Larry Don Powell, at all times material to this action, was the spouse of Kimberly Powell, deceased, and resided in the State of Arkansas, in the County of Garland, Arkansas, where he presently resides.

4. Kimberly Powell, deceased, was an adult residing at all times material to this action and until her death in the State of Arkansas, in the County of Garland, Arkansas. She died on or about March 23, 2014. Plaintiff Larry Don Powell is the personal representative of her estate. See Exhibit 1 (Order Probating Will and Appointing Personal Representative).

5. Defendant Ethicon, Inc. is a corporation, or other entity, organized and/or existing under the laws of the New Jersey, with its principal place of business in Somerville, New Jersey, which at all times material and relevant hereto engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, including the morcellator at issue in this action. It is a citizen of New Jersey according to 28 U.S.C. § 1332.

6. Defendant Johnson & Johnson is a corporation, or other entity, organized and/or existing under the laws of the state of New Jersey, with its principal executive offices in New Brunswick, New Jersey, and its principal place of business in Somerville, New Jersey, and was at all times material and relevant hereto engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, including the morcellator at issue in this action. Defendant Johnson and Johnson is a citizen of New Jersey according to 28 U.S.C. § 1332.

ALLEGATIONS

7. On June 13, 2011, Plaintiff Kimberly Powell had surgery at Baptist Health Medical Center – Little Rock, in Little Rock, Arkansas, which is in Pulaski County. She underwent a robotic laparoscopically-assisted hysterectomy and cystoscopy for sympotomatic uterine leiomyomata and fibroid conditions. She also had a SOlyx mid-urethral sling procedure at the same time. Prior to this surgery, and in preparation for it, all reasonable and standard procedures for detecting cancer were performed on Mrs. Powell, and no cancer was detected in her. There was no evidence that she suffered any form of leiomyosarcoma cancer.

8. The surgeon who performed the above-described surgery on June 13, 2011, utilized a morcellator made and sold by J&J's Ethicon division to cut, shred, and remove much of the uterus from Mrs. Powell. The morcellator is a cutting instrument.

9. After the above-described surgery, it was determined that leiomyosarcoma cancer was present in the tissue shredded by the J&J Ethicon morcellator. After the surgery, Mrs. Powell was diagnosed with the leiomyosarcoma cancer, which had been undetected prior to the surgery. The causal connection between morcellator use and the dissemination, fulmination, and upstaging of leiomyosarcoma was neither appreciated nor discovered until December 18, 2013, once The Wall Street Journal published an article entitled "Doctors Eye Cancer Risk in Uterine Procedure Popular Technique to Remove Growths Comes Under Question." Furthermore, Plaintiffs, like Mrs. Powell, exercising reasonable diligence could not have discovered the causal connection between morcellator use and the dissemination, fulmination, and upstaging of leiomyosarcoma due to Defendants' suppression and concealment of the relevant facts. That suppression and concealment currently is being investigated by the Federal Bureau of Investigation (FBI).

10. Prior to the above-described surgery, the leiomyosarcoma cancer tissue in Mrs. Powell was encapsulated in a uterine fibroid shredded in the surgery by the morcellator made and sold by J&J's Ethicon division. It was undetected before and at the time of the surgery. Other surrounding structures and tissues, also before and at the time of the surgery, including the fallopian tubes and ovaries, appeared normal.

11. The leiomyosarcoma cancer tissue in Mrs. Powell would have remained encapsulated but for the tissue shredding and tissue dissemination of the GYNECARE MORCELLEX™. The device, in cutting and shredding the uterine fibroid, ruptured the capsule containing the cancerous tissue and spread the shredded tissue in Mrs. Powell's abdominal cavity. That action changed the course and prognosis of the leiomyosarcoma cancer which had been encapsulated, upstaging it and profoundly injuring the patient, leading to her death.

12. The cancer suffered by Mrs. Powell was fulminated, disseminated, and upstaged by the Defendants' morcellator, producing the cancer diagnosis following her surgery on June 13, 2011. She was diagnosed with the cancer after the surgery based on an analysis of her uterine and fibroid tissues by the pathologist. The causal connection between morcellator use and the dissemination, fulmination, and upstaging of leiomyosarcoma was neither appreciated nor discovered until an article discussing morcellation as a possible cause was published by the Wall Street Journal in December 2013.

13. Upon information and belief, the above-described J&J Ethicon morcellator was approved for sale and use in the U.S.A. by the United States Food and Drug Administration (FDA) in 2006 and 2010, with the trade name affixed to it by the Defendants being GYNECARE MORCELLEX™. The Defendants' applications to the FDA for approval of the device were

made under the Federal Food, Drug, and Cosmetic Act, § 510(k), as amended, 21 U.S.C. § 360(k).

14. The FDA's approval of the GYNECARE MORCELLEX™ entailed no safety review of the device and was based solely on the FDA's approval of similar devices, so-called "predicate devices," for which no safety studies were conducted.

15. The Defendants, in marketing the GYNECARE MORCELLEX™, undertook and voluntarily assumed a duty to truthfully and fully inform doctors about the device. They undertook and voluntarily assumed this duty in order to obtain sales of the device, but in so doing, they failed to truthfully and fully warn of the device's risks to patients such as Plaintiff's Decedent. This duty of truth and warning ran to Mrs. Powell's surgeon, and the Defendants knew or should have known that fulfillment of the duty was necessary to protect Mrs. Powell by providing her surgeon with the information necessary to safely treat her.

16. The Decedent and her surgeon properly relied on the Defendants' representations about the device. The Defendants, by failing to exercise due care in performing their duty to properly warn of the device's risks, profoundly increased the danger and risk to the Decedent, resulting in her death.

17. The Defendants falsely conveyed that their morcellator was safe for use for the Decedent's surgery, negligently and proximately causing injury to and the death of the Decedent, resulting in actual loss and damage.

18. Had the GYNECARE MORCELLEX™ used in Mrs. Powell's surgery in June, 2011, not disseminated and fulminated cancer cells throughout her abdomen, she would not have suffered and been diagnosed with upstaged leiomyosarcoma cancer. The morcellator caused this specific cancerous condition, profoundly and gravely injuring her. She died from the injury on

or about March 23, 2014. The death certificate noted the leiomyosarcoma with metastasis as a cause of death.

19. In April 2014, the FDA announced a black-box warning for the GYNECARE MORCELLEX™ which cautioned physicians not to use the morcellator for removal of uterine tissue containing suspected fibroids in patients who are peri- or post- menopausal. Mrs. Powell was peri- or post- menopausal when the device was used to shred uterine fibroids in her, and the Defendants did not warn her surgeon that it should not be used for that purpose on her.

20. Prior to her death, Mrs. Powell, suffered extreme physical pain and mental anguish from the leiomyosarcoma cancer upstaged by the GYNECARE MORCELLEX™. That pain and suffering was caused by the morcellator.

21. The Plaintiff, due to his spouse's injury and death, suffered and will continue to suffer harm, including the loss of consortium and medical costs for the hospitalization, treatment, palliative care, other medical care, and death of his spouse.

22. Mrs. Powell, prior to her death, underwent several additional procedures related to the disseminated cancer and further spread. On July 5, 2011 she underwent a procedure related to the spread of cancer in her omentum cavity. On May 31, 2012, a laparotomy was performed for tumor removal and reduction. She underwent an additional procedure on January 15, 2013, again, after the leiomyosarcoma cancer was disseminated and upstaged by the Defendants' morcellator. The procedure revealed cancer cells in various areas of her vaginal cuff, at areas around her ureters, and throughout the omentum. Abdominal washings at that time showed malignant cells consistent with leiomyosarcoma. Invasion into the lymphovascular system was noted. These note just a few of the procedures and treatments Mrs. Powell underwent, there were many others.

23. After being diagnosed with the upstaged leiomyosarcoma cancer, Mrs. Powell underwent aggressive chemotherapy treatments in an effort to treat her upstaged cancer. Despite that treatment, the cancer continued to spread, with CT examinations of her chest and pelvis indicating the spread in new masses within her right hepatic lobe and mesentery. As a result, she experienced on a daily basis the following debilitating effects of the cancer and the cancer-drug therapy: fatigue, pain, inflammation, swelling, insomnia, and gastrointestinal distress. Her treatments continued thereafter, and her pain and suffering increased, ending in her death. All of those consequences and events were caused by the Defendants' morcellator.

24. Had the GYNECARE MORCELLEX™ not disseminated and fulminated cancer throughout the Decedent's abdomen, cancerous tissue in her fibroids would have remained well confined and encapsulated. The tissue would not have spread through the abdomen generally, and the cancer would not have been disseminated, fulminated, and upstaged.

25. The Defendants knew, or should have known, prior to Mrs. Powell's morcellation surgery in June, 2011, of the risk of disseminating unsuspected/undiagnosed cancers with the normal and customary use of their morcellator.

26. The Defendants failed to adequately warn about the true risk of dissemination and fulmination of cancer from the use of the GYNECARE MORCELLEX™. Despite their knowledge of that true risk and of their own failure to adequately warn of it, the Defendants failed to make the instrument safe for its intended use, making it unsafe for that use.

27. The Defendants designed, manufactured, marketed, and sold the GYNECARE MORCELLEX™ for uterine surgery, specifically for cutting, shredding, and removing the uterus and uterine fibroids. The Defendants therefore knew that they had marketed and promoted the use of their morcellator for surgical cases specifically including Mrs. Powell's June, 2011

surgery. Because of their failure to adequately warn surgeons of the risk of morcellator use and their failure to produce a safe, closed system for use with their morcellator to prevent dissemination of undetected cancers, Mrs. Powell suffered the harm described. The harm was completely avoidable and would have been avoided but for the Defendants' breaches of duties, their misrepresentation, and their breaches of the warranties on the morcellator.

28. The Defendants' applications to the FDA for approval of the GYNECARE MORCELLEX™ failed to warn about the true risk of dissemination and fulmination of cancer from the use of the device. The applications failed to properly recommend use of an effective closed system tissue bag.

29. In 2005, the Defendants published the product manual (a/k/a instructions for use, or "IFU") for the GYNECARE MORCELLEX™ which was utilized in Mrs. Powell's morcellation surgery in June, 2011. The manual is designated by the Defendants as "IFU-64-002 Rev. B," and the instructions it provides for use of the device contain no warning against use of the morcellator in cases of this type, namely where a hidden, unsuspected, and undetected leiomyosarcoma cancer would be disseminated and upstaged by the device. The instruction is as follows:

> The use of 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. As morcellation may affect endometrial pathologic examination, preoperative evaluation of the endometrium should be considered. Should malignancy be identified, use of the GYNECARE Morcellex Tissue Morcellator may lead to dissemination of malignant tissue.

30. No later than 2006, the year after publication of the above instruction in 2005, the Defendants received specific notice that hidden and undetected leiomyosarcoma cancers would be disseminated and upstaged by use of the GYNECARE MORCELLEX™ utilized in Mrs. Powell's morcellation surgery in June, 2011. This notice was given to them by a surgical

pathologist, who specifically informed them of the danger that their device would disseminate and upstage undetected leiomyosarcoma cancer. The Defendants failed to notify the FDA of this notice and danger, and they took no action to warn surgeons of the danger and did nothing to make the device safe for use.

31. The above instruction published by the Defendants in their 2005 manual for the device appears again in their IFU-64-002 Rev G, which is the manual, or IFU, for the device they published in 2013, after Mrs. Powell's morcellation surgery. The instruction in 2013 is only slightly revised from 2005 and also contains no warning against use of the morcellator in cases of Mrs. Powell's type, where a hidden and undetected leiomyosarcoma cancer would be disseminated and upstaged by the device. The 2013 instruction states:

> The use of a laparoscopic 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. As morcellation may affect endometrial pathologic examination, preoperative evaluation of the endometrium should be considered. Should malignancy be identified, use of the GYNECARE MORCELLEX™ Tissue Morcellator may lead to dissemination of malignant tissue.

32. The Defendants failed to adequately warn about the true risk of dissemination and fulmination of cancer from the use of the GYNECARE MORCELLEX™. Despite their knowledge of that true risk and of their own failure to adequately warn of it, they failed to make the instrument safe for its intended use.

33. Mrs. Powell suffered the upstaged cancer because the Defendants failed to adequately warn surgeons of the true risk of morcellator use and because they failed to adequately recommend or provide a safe, closed system tissue bag for use with the GYNECARE MORCELLEX™ to prevent dissemination of an undetected cancer.

34. Upon information and belief, in the United States in 2011, the year of the morcellation surgery at issue, the GYNECARE MORCELLEX™ and power morcellators similar to it were used in approximately 50,000 to 60,000 surgeries of the same type performed on Mrs. Powell.

35. The Defendants' instructions for use of the GYNECARE MORCELLEX™, as those instructions appear in the manuals, or IFUs, for the device (as described above), are insufficient, misleading, and negligent in that they wrongly convey that detection of cancerous tissue by conventional and standard procedures and techniques prior to morcellation is feasible and likely. It is not. In at least one in 350 cases, Mrs. Powell's included, detection of such cancerous tissue is not feasible or likely, as Defendants knew or should have known. So their instruction about use of a tissue extraction bag when cancer is detected and suspected did not and categorically could not eliminate the risk of dissemination of uterine cancer in Mrs. Powell's case. The Defendants' instructions in fact promoted that risk and ensured harm to Mrs. Powell by (a) providing a false and inadequate warning, and (b) conveying that the device could be used safely in all cases according to the instructions.

36. Neither the Defendants' applications to the FDA to market the device nor their instructions about the use of it advised Mrs. Powell's surgeon that in cases such as hers, a containment system should be used, namely a laparoscopic tissue bag to contain shredded tissue fragments and thereby prevent dissemination of cancer in cases where cancer is unsuspected and undetected.

37. Her surgeon reasonably relied on the Defendants' information about the morcellator and, upon information and belief, her surgeon would not have used it on her, or

would not have used it on her without a containment system, had the Defendants' information about the product been adequate, true, effective, and not misleading.

38. A surgical tissue bag and method was awarded a patent on August 6, 1991, establishing notice to the Defendants of the feasibility and effectiveness of a containment system long before the morcellation surgery on Mrs. Powell. The patent was submitted to the United States Patent office in June of 1990, long before the Section 510(k) applications to the FDA by the Defendants for approval of the GYNECARE MORCELLEX™. The patent background information states:

> 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. As a result, the debulking of large malignant tissue volumes percutaneously through an access sheath presents significant morbidity risks to the patient.

39. The patent filing also states that "containment of the tissue within the bag also prevents the spread of malignant cells to healthy tissue in the body cavity."

40. The Defendants failed to monitor post-surgical outcomes for disseminated cancer caused by their GYNECARE MORCELLEX™ and failed to monitor, analyze and report bad outcomes from the use of the morcellator. The Defendants failed to report post-surgical outcomes, as required, to the FDA.

COUNT I - NEGLIGENCE

The allegations above are incorporated by reference to support this Count.

41. The Defendants owed a duty to manufacture, compound, label, market, distribute, supply, and/or sell products, including instruments for uterine morcellation, specifically the

GYNECARE MORCELLEX™, in such a way as to avoid harm to persons upon whom they are used, including Mrs. Powell, and to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

42. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as Mrs. Powell, so as to avoid harm, and they breached that duty, causing her injury and ultimately her death.

43. 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, the GYNECARE MORCELLEX™, both generally and in the following particular respects:

a. failing to conduct adequate and appropriate testing of instruments such as the GYNECARE MORCELLEX™, specifically including, but not limited to, products used for uterine morcellation;

b. putting products used for uterine morcellation such as the GYNECARE MORCELLEX™ on the market without first conducting adequate testing to determine possible side effects;

c. putting products used for uterine morcellation such as the GYNECARE MORCELLEX™ on the market without adequate testing of its dangers to humans;

d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, such as the GYNECARE MORCELLEX™, which testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the GYNECARE MORCELLEX™ which indicated such products potential harm to humans;

f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation, such as GYNECARE MORCELLEX™;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products' potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the GYNECARE MORCELLEX™, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation such as the GYNECARE MORCELLEX™, for use on patients given their knowledge and experience of such products and potential harmful effects;

l. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the GYNECARE MORCELLEX™;

m. placing and/or permitting the placement of the products used for uterine morcellation, specifically the GYNECARE MORCELLEX™, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

n. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the GYNECARE MORCELLEX™, to be harmful to humans;

o. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients, including the GYNECARE MORCELLEX™;

p. disregarding the safety of users and consumers of products used for uterine morcellation, including Plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

q. disregarding the safety of users and consumers of the products used for uterine morcellation, including Plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

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

s. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

t. failing to remove products used for uterine morcellation from the stream of commerce;

u. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

v. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods;

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

x. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;

y. failing to use due care under the circumstances;

z. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the GYNECARE MORCELLEX™.

aa. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the GYNECARE MORCELLEX™ for disseminated cancer;

bb. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the GYNECARE MORCELLEX™ to the FDA;

cc. failing to respond to multiple published studies describing the risk of disseminated cancer and up-staging of cancer with morcellator use;

dd. failing to utilize, include, or adequately recommend the use of a closed system such as a tissue bag to contain morcellated tissue fragments and thereby prevent the relevant risk known to Defendants from use of their product, namely dissemination of uterine cancer, the adverse event which specifically occurred in Mrs. Powell's case;

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

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

44. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff's Decedent was injured, suffered profoundly, and died, and Plaintiff suffered financial losses and other harm.

45. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in his favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT II - STRICT PRODUCTS LIABILITY

The allegations above are incorporated by reference to support this Count.

46. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, specifically the GYNECARE MORCELLEX™, which Defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiff Kimberly Powell for her injuries which they directly and proximately caused.

47. The Defendants proximately and directly caused her injuries by failing to properly and adequately design the product used for uterine morcellation, specifically the GYNECARE MORCELLEX™, to include an intraperitoneal tissue bag to contain the morcellated tissue so as to prevent dissemination and the spread of malignant cancer cells in the abdominal cavity.

48. The GYNECARE MORCELLEX™ was used in the surgery performed on Mrs. Powell in June, 2011. During her surgery the GYNECARE MORCELLEX™ was used to

morcellate tissue for removal during the laparoscopic procedure. Shortly after this procedure, Mrs. Powell learned that the morcellated tissue was cancerous.

49. The GYNECARE MORCELLEX™ is unreasonably dangerous for use to morcellate uterine tissue, because the device spreads and fulminates previously unsuspected and undetected cancer throughout the abdominal cavity of surgical patients like Mrs. Powell.

50. Defendants were aware of the defect and danger of their morcellator and of the risk of harm it posed to patients including Mrs. Powell. They placed it on the market anyway, knowing that it would be used without inspection for defects, and the device proved to have a defect which caused Mrs. Powell's injury.

51. The Plaintiff's injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, specifically the GYNECARE MORCELLEX™, without proper and adequate warnings regarding the potential for said products' harm to humans and as otherwise set forth above, when said Defendants knew or should have known of the need for such warnings and/or recommendations.

52. Defendants failed to monitor, analyze and report adverse outcomes stemming from the use of the GYNECARE MORCELLEX™ and disseminated cancer. They failed to report these adverse outcomes and the dissemination of cancer from the use of the GYNECARE MORCELLEX™ to the FDA.

53. The Defendants failed to respond to reports and multiple published studies that predate their Section 510(k) application to the FDA in 2010 which describe the risk of disseminated cancer and up-staging of cancer with morcellator use.

54. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in their favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT III - FRAUDULENT MISREPRESENTATION AND OMISSION

The allegations above are incorporated by reference to support this Count.

55. Upon information and belief, the Defendants' statements about the GYNECARE MORCELLEX™, as the statements appear in the manuals which accompanied the device, wrongly and falsely convey that the device may be used safely in surgeries of the type performed on Mrs. Powell without a tissue bag to contain fragmented tissue. The Defendants knew or should have known that (a) the device is unsafe for use without containment of tissue fragments even when cancer is not suspected and detected by standard procedures prior to the morcellation surgery, and (b) in at least 1 in 350 cases, Mrs. Powell's included, the device will disseminate and fulminate cancer which is not suspected and detected prior to the surgery.

56. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the GYNECARE MORCELLEX™, owed a duty to provide accurate and complete information regarding said instruments. They breached that duty.

57. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the GYNECARE MORCELLEX™, owed a duty to monitor, analyze and report adverse outcomes stemming from the use of the GYNECARE MORCELLEX™. They breached that duty.

58. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the GYNECARE MORCELLEX™, owed a duty to monitor and respond to reports and multiple published studies that describe the true risk of disseminated cancer and up-staging of cancer with morcellator use. Such information placed Defendants on notice of the above-described risk to patients such as Mrs. Powell no later than 2006, five years or more before her morcellation surgery in June, 2011, where that risk materialized and gravely injured her. The Defendants therefore breached their duty to her by failing to adequately warn of the true risk.

59. Prior to Plaintiff's surgery in June, 2011, Defendants fraudulently misrepresented that the use of their GYNECARE MORCELLEX™ for uterine morcellation was safe and effective.

60. There is no warning in the Defendants' applications to the FDA for Section 510(k) approval of the device or in their device instructions about the potential dissemination of undetected cancer. The potential dissemination of undetected cancer was a problem known to the Defendants prior to Mrs. Powell's surgery in June, 2011. They did nothing to warn surgeons of the problem and of the risk to patients such as Mrs. Powell.

61. Defendants had a duty to provide Mrs. Powell, her physicians, and other patients and doctors concerned with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold, including the GYNECARE MORCELLEX™. They failed to perform that duty, omitting material information about the instrument's risks.

62. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance

by purchasing and using the GYNECARE MORCELLEX™. The Plaintiff's doctor, the Plaintiff, and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the GYNECARE MORCELLEX™, including for Mrs. Powell's morcellation surgery.

63. Defendants' representations and omissions regarding use of its uterine morcellation device were a direct and proximate cause of the injury to and death of the Plaintiff's Decedent, specifically causing the disseminated and fulminated cancer, which caused her suffering and death.

64. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in his favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT IV - BREACH OF EXPRESS WARRANTY

The allegations above are incorporated by reference to support this Count.

65. In the advertising and marketing of their products for uterine morcellation which they directed to hospitals, consumers, and physicians – Mrs. Powell's surgeon included – the Defendants warranted that the GYNECARE MORCELLEX™ was safe for use on patients such as Mrs. Powell, which had the natural tendency to induce her surgeon to use it in her case.

66. The aforesaid warranty was breached by Defendants in that the GYNECARE MORCELLEX™ was unsafe for use in Mrs. Powell's case, constituted a serious danger to her, and killed her.

67. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff's Decedent was injured, suffered profoundly, and died, and Plaintiff suffered financial losses and other harms and damages.

68. Wherefore, on this Count, Plaintiff respectfully request that the Court enter judgment in his favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT V - BREACH OF IMPLIED WARRANTIES

The allegations above are incorporated by reference to support this Count.

69. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the GYNECARE MORCELLEX™ used for uterine morcellation.

70. At all relevant times, Defendants intended that their products for uterine morcellation, including the GYNECARE MORCELLEX™, be used in the manner that Mrs. Powell's surgeon in fact used it, and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

71. Defendants breached various implied warranties with respect to the GYNECARE MORCELLEX™ used for Mrs. Powell's morcellation surgery, by:

a. representing through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the GYNECARE MORCELLEX™ was safe;

b. withholding and concealing information about the substantial risks of serious injury and/or death associated with the GYNECARE MORCELLEX™;

c. representing that the GYNECARE MORCELLEX™ was as safe and/or safer than other alternative surgical approaches that did not include the use of the said product;

d. concealing information which demonstrated that said product was not safer than alternatives available on the market;

e. representing that morcellation with the GYNECARE MORCELLEX™ was more efficacious than other alternative surgical approaches and techniques; and

f. concealing information regarding the true efficacy of said product.

72. In reliance upon Defendants' implied warranties, Plaintiff's surgeon used said GYNECARE MORCELLEX™ as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

73. Defendants breached their implied warranties to Plaintiff in that said GYNECARE MORCELLEX™ used for uterine morcellation was not of merchantable quality, safe and fit for their intended use, or adequately tested.

74. As a direct and proximate consequence of Defendants' breach of implied warranties and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Plaintiff's Decedent was injured, suffered profoundly, and died, and Plaintiff suffered financial losses and other harm.

75. Wherefore, on this Count, Plaintiff respectfully request that the Court enter judgment in his favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT VI - LOSS OF CONSORTIUM

The allegations above are incorporated by reference to support this Count.

76. Plaintiff claims damages for loss of consortium as a consequence of the injury to and death of his wife, such injury and death having been caused directly and proximately caused by the acts, omissions, and misconduct of the Defendants. The acts, omissions, and misconduct

of the Defendants, as alleged, are the proximate cause of the loss and harm suffered by the Plaintiff.

77. Wherefore, on this Count, the Plaintiff respectfully requests that the Court enter judgment in his favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, to the utmost amount allowed by law, to include damages for the Decedent's pain and suffering, damages for wrongful death, emotional distress, loss of enjoyment of life, loss of consortium, loss of society, and other non-economic damages in an amount to be determined by a jury at trial of this action;

2. Medical expenses and other economic damages in an amount to be determined by a jury at trial of this action;

3. All punitive damages allowed by law, to the utmost amount, to be determined by a jury at trial of this action;

4. Restitution and disgorgement of profits;

5. Reasonable attorneys' fees;

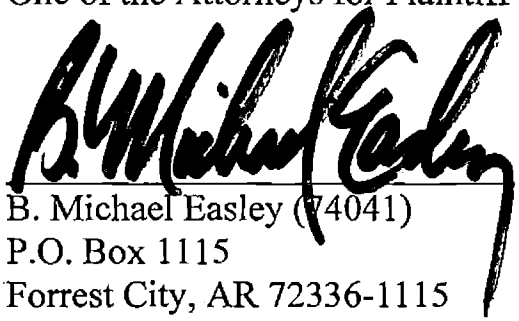
6. The costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff demands a jury to decide all triable issues.

EASLEY AND HOUSEAL, PLLC
One of the Attorneys for Plaintiff



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FILED

IN THE CIRCUIT COURT OF GARLAND COUNTY, ARKANSAS
PROBATE DIVISION

2015 FEB 18 AM 10 18

SARAH SMITH
GARLAND CO. CLERK

IN THE MATTER OF THE ESTATE OF KIMBERLY ANNE POWELL, DECEASED

NO. PR15-98-I

BY

ORDER PROBATING WILL AND APPOINTING PERSONAL REPRESENTATIVE

On this date, comes on for hearing the petition of Larry Don Powell, for probate of the Will of Kimberly Anne Powell, deceased, and for the appointment of personal representative of the estate, and upon consideration of such petition, and the facts and evidence in support thereof, the Court finds:

1. That no demand for notice of proceedings to probate the decedent's Will or for the appointment of a personal representative of the estate has been filed herein, the petition is not opposed by any known person, and the same may be heard and decided forthwith.

2. That Kimberly Anne Powell, who resided at 30 Sergio Drive, Hot Springs Village, Arkansas, died at home, on March 23, 2014.

3. That this Court has jurisdiction and venue properly lies in this County.

4. That the instrument offered for probate was executed in all respects according to law when the decedent was competent to do so and acting without undue influence, fraud or restraint, and has not been revoked.

5. That the Will of the decedent nominates Larry Don Powell, to serve as personal representative without bond, and he is a proper person to so serve.

It is, therefore, CONSIDERED, ORDERED and ADJUDGED that the proffered instrument be and hereby is admitted to probate as the Last Will of the decedent, that Larry Don Powell be and hereby is appointed personal representative without bond, and that Letters Testamentary shall be

EXHIBIT "1"

issued to said personal representative upon filing of his Acceptance of Appointment.

CIRCUIT JUDGE

2/17/2015
DATE

Prepared by:

HYDEN, MIRON & FOSTER, PLLC

By:

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501-376-8222/501-376-7047 (fax)
Attorneys for Petitioner

OFFICIAL PROBATE FORM 11 PROBATE CODE, SEC. 71
This Form Has Been Officially Prescribed by the Supreme Court of Arkansas for Use Under the Probate Code, Act 140 of 1949 Acts of Ark.

IN THE CIRCUIT COURT OF GARLAND COUNTY, ARKANSAS
PROBATE DIVISION
DIV I

IN THE MATTER OF THE ESTATE OF
KIMBERLY ANNE POWELL, Deceased

PR-2015-98

LETTERS TESTAMENTARY

BE IT KNOWN:

THAT: Larry Don Powell, whose address is 30 Sergio Dr., Hot Springs Village, AR 71909 having been duly appointed Personal Representative of the estate of KIMBERLY ANNE POWELL, deceased, who died on or about March 23, 2014, and having qualified as Personal Representative is hereby authorized to act as Personal Representative for and in behalf of the estate and to take possession of the estate's property as authorized by law.

ISSUED this 17th day of February, 2015.

(SEAL)

SARAH SMITH, Clerk

By: Judy Stockdale, Deputy Clerk

State of Arkansas)
County of Garland)ss February 18, 2015

I Hereby Certify this to be a True Copy of the Original Letters Testamentary Issued in this Probate Court on February 17, 2015. And That Same Is Now In Full Force and Effect.

SARAH SMITH, CLERK By: Judy Stockdale, D.C.