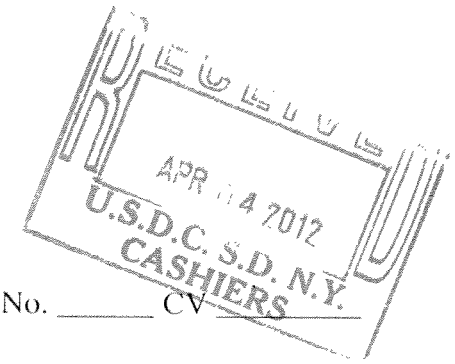
JUDGE SWEET

12 CIV 2597

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



GILMORE McCALLA, as Administrator of the Estate of KIMBERLEY McCALLA,

Plaintiff,

-against-

INTUITIVE SURGICAL, INC.,

Defendant.

Index No. _____ CV _____

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff, complaining of the defendant by his attorneys Rheingold Valet Rheingold McCartney & Giuffra LLP respectfully alleges, upon information and belief, the following:

THE PARTIES

1. That at the time of her death on August 25, 2010, the decedent KIMBERLEY McCALLA was a resident of and domiciled in the County of the Bronx, City and State of New York.

2. The plaintiff GILMORE McCALLA is a resident of and domiciled in the County of the Bronx, City and State of New York.

3. The defendant INTUITIVE SURGICAL, INC. (hereinafter "INTUITIVE") is a foreign business corporation, duly organized and existing under and by virtue of the laws of the State of Delaware.

4. Upon information and belief, the defendant INTUITIVE is a foreign corporation with its principal place of business being located in the State of California.

JURISDICTION AND VENUE

5. Jurisdiction for this action in the United States District Court arises under 28 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on complete diversity of citizenship in that the estate representative's permanent residence and domicile is in the Southern District of New York and the defendant is a citizen of a foreign state. The amount in controversy exceeds $75,000 exclusive of costs and interest.

GENERAL ALLEGATIONS

6. Plaintiff GILMORE MCCALLA was appointed administrator of the Estate of KIMBERLEY McCALLA, his daughter, on or about March 1, 2011 by the Surrogate of Bronx County.

7. Plaintiff's intestate KIMBERLEY McCALLA died on August 25, 2010 as the result of, among other things, injuries sustained by the use of the da Vinci surgical robot manufactured and sold by defendant INTUITIVE.

8. Defendant INTUITIVE is a Delaware corporation with its principal place of doing business in Sunnyvale, CA.

9. Defendant INTUITIVE is a publically traded company on the NASDAQ exchange, with a current market value of more than two billion dollars.

10. Defendant designed, manufactured, tested, sold, promoted and labeled the da Vinci surgical robot.

11. On its website defendant asserts that it is the global technology leader in surgical robotic products.

12. The said robotic device is used in hospitals for a variety of surgeries, including gynecological, and including therein hysterectomies.

13. Defendant has promoted its device as (a) safe, and (b) safer than other comparative methods of surgery including, in the case of hysterectomies, laparoscopy, vaginal surgery and open surgery.

14. Defendant utilizes prominent websites aimed at consumers, seeking to create demand for the use of its robotic device by patients who consult surgeons.

15. Defendant sold it device through a calculated program of intimidation and market management, forcing hospitals and physicians to purchase it in order to appear to be competitive, and creating a fear in their minds that if they did not have this technology they would lose business to competitors.

16. Defendant reinforced its calculated program, as stated in the preceding paragraph, by placing, on its website for potential patients, names of certain physicians who had performed 20 surgeries with the device.

17. The use of defendant's robotic device in surgery presents substantial risks of complications and injuries, including burns, tears, dehiscences, bleeding, hematomas, sepsis, and fistulas.

18. More specifically, defendant's robotic device can cause damage to the bowel, blood vessels, arteries, ureters, and vaginal cuff.

19. In addition, due to lengthened time of surgery, patients are unnecessarily exposed to anesthesia for a dangerous period of time.

20. On occasion these complications and injuries cause and/or contribute to the untimely and premature death of the patient.

21. Defendant is aware of the aforesaid risks and complications associated with the use of the said robotic device.

22. Defendant does not provide adequate warnings to physicians and patients about the risks and complications associated with the use of its robotic device.

23. Defendant has not done, nor sponsored, adequate testing on its said device before and after marketing it to determine whether in random tests its said device is either safer or more effective or otherwise superior to other surgical and laparoscopic methods to which it compares itself.

24. Defendant has not done adequate post marketing surveillance of complications and injuries which have occurred in actual practice.

25. Defendant has not done, nor sponsored, any testing as to long-term outcomes, in comparison to other surgical and laparoscopic methods.

26. Defendant has not revealed, through publications or reports to the Food and Drug Administration and other governmental bodies, the true extent of complications and injuries which have occurred in actual practice.

27. Defendant has suppressed reports and complaints of complications and performance errors due to the use of its said device.

28. Defendant does not adequately train physicians nor proctor them properly on the use of its device, thereby inducing them to cause complications and injuries which would be avoided in the hands of properly trained physicians.

29. Defendant represents that they will have skilled technicians in the operating room or on emergency call in the event of problems arising with its said device, but often has neglected to do so.

30. Defendant has over-promoted its device to hospitals, physicians and the public, including potential consumers, combined with minimizing the risks and complications associated with its use.

31. The device is defective in that it relies upon the use of monopolar energy to cut, burn and cauterize tissue, whereas safer methods are available such as bipolar energy and harmonic scalpel, which would reduce substantially the risk of complications.

32. The device has inadequate insulation for its arms thereby allowing electrical current to pass into tissue outside of the operative field.

33. The insulation on the shafts of the said device becomes torn and worn in places, without the awareness of the physician user, allowing electrical current to pass into tissue outside of the operative field, causing damage.

34. Defendant has failed to warn users and consumers of the said robotic device about the inadequate insulation on the arms and the potential for electrical current to pass into tissue outside of the operative field.

35. Due to design defects, defendant's devices have malfunctioned during the course of operative use causing injury, including the necessity of converting the procedure into open surgery.

36. Defendant has failed to warn users and consumers of its said device of the design flaws stated in the preceding paragraphs, although it has reached out directly to consumers to promote its asserted advantages.

37. Defendant has obtained and continues to maintain approval of the uses of its device from the Food and Drug Administration by failing to fully inform them of its knowledge of risks and complications associated with the use of its device.

38. KIMBERLEY MCCALLA was admitted to Montefiore Medical Center on August 12, 2010 for the performance of a hysterectomy due to a diagnosis of adenoma/carcinoma.

39. On August 12, 2010 surgery utilizing defendant's device was performed on KIMBERLEY MCCALLA consisting of a total laparoscopic hysterectomy, bilateral salpingo-oophorectomy and pelvic node dissection.

40. Emergency surgeries performed on KIMBERLEY MCCALLA on August 23, 2010, August 24, 2010 and August 25, 2010 revealed that there had been a burn of the right external iliac artery which was pumping blood into the body cavity causing, among other things, bowel ischemia "incompatible with life."

41. KIMBERLEY MCCALLA was pronounced dead shortly after the final emergency surgery on August 25, 2010.

FIRST CAUSE OF ACTION - WRONGFUL DEATH – STRICT LIABILITY

42. Defendant placed into the stream of commerce its aforesaid device which was defective in design, as previously pleaded.

43. Defendant placed into the stream of commerce its aforesaid device which was defective in its labeling and warnings, as previously pleaded.

44. Defendant placed into the stream of commerce its aforesaid device which was defective in its testing and approval, as previously pleaded.

45. At the time the device left the possession of defendant it was in an unreasonably dangerous and defective condition.

46. That by reason of the foregoing and defendant's aforesaid conduct, among other things, the plaintiff's intestate suffered injuries which caused, hastened and/or precipitated her untimely and premature death on August 25, 2010 at 24 years of age.

47. Plaintiff has incurred and is liable for certain expenses, including hospital and medical treatment, and funeral and burial expenses, as a result of, among other things, defendant's conduct.

48. Plaintiff's intestate left her surviving her father GILMORE MCCALLA and her husband SHAWN COLLINS as distributees and that said distributees have suffered substantial pecuniary injuries by reason of the death of KIMBERLEY MCCALLA under the Estates, Powers & Trusts Law, all to their damage.

49. By reason of the death of KIMBERLEY MCCALLA, plaintiff, GILMORE MCCALLA has been and will continue to be deprived of the love, support, services and society of his deceased daughter, all to his damage.

50. As a result of its said conduct, defendant has become strictly liable to plaintiff.

51. Defendant's conduct in continuing to market, sell and distribute the aforesaid devices after obtaining knowledge they were defective and not performing as represented and intended, showed complete indifference to and/or a conscious disregard for the safety of others justifying an award of punitive damages for aggravating circumstances in such a sum which will serve to deter defendant and others from similar conduct in the future.

SECOND CAUSE OF ACTION - NEGLIGENCE

52. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action contained herein as if the same were set forth more fully at length herein.

53. Defendant was careless in the design, testing, manufacturing, labeling and promotion of its aforesaid device, as pleaded in previous paragraphs.

54. In specific, defendant failed to warn users and consumers of the risk of complications associated with the use of its said device, including the damage to the bowel and artery which was a proximate cause of decedent's death.

55. Defendant did not proctor and/or properly instruct decedent's surgeons and attending staff as to the safe use of its device nor how to detect complications which its said device causes and is known to cause.

THIRD CAUSE OF ACTION - FRAUD

56. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

57. Defendant misrepresented the safety and comparative efficacy of its device, upon which decedent's surgeons relied, to decedent's detriment.

58. Defendant misrepresented the safety and comparative efficacy of its device, upon which the hospital and surgery department where decedent was operated on relied, in purchasing and using the device, to decedent's detriment.

59. Further, defendant concealed from consumers and users, including those mentioned in the preceding two paragraphs, the risks of complications of which it was aware,

which would have been material to consumers and users in making the decision to use the said device.

60. Further, defendant suppressed reports of adverse outcomes with the use of its device, which would have been material to consumers and users in making the decision to use the said device.

61. Further, defendant over-promoted its device and minimized its risks, for the purpose of making sales of its device, its maintenance, and the use of replaceable parts, and skewed the cost-benefit ratio inaccurately in its favor.

62. The said conduct was so willful, wanton, malicious and reckless that it merits the imposition of punitive damages.

FOURTH CAUSE OF ACTION - BREACH OF WARRANTIES

63. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

64. Defendant made express warranties of safety to the buyers and consumers of the device utilized during decedent's surgery, upon which the buyers and users, as agents of decedent, relied, to decedent's detriment.

65. By selling the said device, defendant made implied warranties of safety, merchantable quality, and fitness for use, which was breached when plaintiff's intestate was injured and died.

FIFTH CAUSE OF ACTION - CONSCIOUS PAIN AND SUFFERING

66. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

67. Following the robotic surgical procedure performed on August 12, 2010 and continuing up until the time of her death on August 25, 2010 the plaintiff's intestate was caused to and did suffer and experience significant, exquisite and excruciating conscious pain and suffering, due to, among other things, the fault of defendant as previously pleaded.

68. Further, during the aforesaid two week period, the decedent reported that she felt that she was dying. She was continually receiving pain control medication, without good effect.

CPLR 1602 EXCEPTIONS

69. Plaintiff's lawsuit falls within one or more of the enumerated exceptions of Article 1602 of the N.Y. C.P.L.R., specifically sections 1602(1), 1602(2)(iv), 1602(4), 1602(7), 1602(8), 1602(10), 1602(11) and 1602(12).

WHEREFORE, plaintiff demands of the defendant:

1. On the First through Fourth Causes of Action for Wrongful Death, the sum of $50 million per each Cause of Action;
2. On the Fifth Cause of Action for Conscious Pain and Suffering, the sum of $50 million;
3. On the claim for punitive damages in each cause of action, a total of $100 million; and

All together with the interest, costs and disbursements of this action.

Dated: New York, New York
April 3, 2012

Respectfully submitted,

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