

**Eileen Guckin and Stephen
Guckin,934 Herbert Street
Philadelphia, PA 19124**Plaintiffs,

**COURT OF COMMON
PLEASPHILADELPHIA COUNTY**June
Term, 2002Docket Number: 001425

vs.**Deborah Nagle, individually and
as anEmployee of Tenet Healthcare:
Corporationand Graduate
Hospital, Inc.1800 Lombard
Avenue Philadelphia, PA 19146**
and

**Graduate Hospital, Inc.1800
Lombard AvenuePhiladelphia, PA
19146**

and
**Tenet Healthcare Corporation3820
State StreetSanta Barbara, CA
93105**

and
**Curon Medical, Inc.735 Palomar
AvenueSunnyvale, CA 94085**

and
**John Does 1 through 12 and
individualIRB members of
Graduate Hospital:
Defendants.**

Defendant.:

COMPLAINT - CIVIL ACTION

1. Plaintiffs Eileen Guckin and Stephen Guckin are husband and wife, with a residence at 934 Herbert Street, Philadelphia, PA 19124.

2. Defendant Deborah A. Nagle, M.D., is an individual and employee of Tenet Healthcare Corporation and Graduate Hospital, Inc. where she practices surgery. Her business address is Graduate Hospital, Inc., 1800 Lombard Avenue, Philadelphia, PA 19146.

3. At all times relevant hereto, Dr. Nagle was the principal investigator in a clinical trial studying the safety and efficacy of a device known as the Secca System, designed to remedy problems associated with fecal incontinence.

4. Defendant Tenet Healthcare Corporation is believed to be a California corporation with an address at 3820 State Street, Santa Barbara, CA 93105 and is believed to be the owner of the Graduate Hospital, located at 1800 Lombard Ave., Philadelphia, PA 19146.

5. Defendant Graduate Hospital, Inc. ("Graduate Hospital") is believed to be a Pennsylvania corporation with an address at 1800 Lombard Ave., Philadelphia, PA 19146.

6. Defendant, Curon Medical, Inc., ("Curon") is believed to be a California corporation with an address at 735 Palomar Avenue, Sunnyvale, CA 94085. Curon Medical, Inc. is the manufacturer of the Secca System.

7. Defendants John Does 1 through 12 are individual members of the Institutional Review Board of Graduate Hospital ("IRB Defendants") whose name and address are currently unknown at this time.

8. In the winter of 2000, Eileen Guckin met with her urologist and complained that she had been experiencing episodes of fecal incontinence for many years. Accidents stemming from her inability to properly control her bowels, however, were only occasional, and she was able to maintain enough control so that she could rush to the bathroom in order to avoid an accident. She was not dependent on adult diapers, nor was she restricted to a lifestyle that required her to be in a state of constant fear over her condition.

9. The urologist recommended Ms. Guckin visit with defendant Dr. Nagle, a colorectal surgeon practicing at Graduate Hospital.

10. In the spring of 2000, Dr. Nagle advised Ms. Guckin of a new procedure she said she was studying at Graduate Hospital, involving the Secca System, a device manufactured by Curon and intended to alleviate or decrease the symptoms of fecal incontinence by delivering radiofrequency energy to the muscles of the anal canal.

11. Dr. Nagle represented that the procedure was performed in a 10-person study in California which proved its success.

12. Dr. Nagle further represented the procedure was the best therapeutic alternative for Ms. Guckin and that, even if unsuccessful, her condition would not deteriorate as a result of the

procedure.

13. In August of 2000, Dr. Nagle represented that Ms. Guckin had qualified to be included in the study at Graduate Hospital and that she would receive \$300 for participating.

14. On August 18, 2000, Ms. Guckin was presented with an informed consent document, a copy of which is attached as Exhibit "A." Neither Dr. Nagle, the principal investigator, nor any other qualified member of the clinical trial team participated in the consent process. Instead, no one other than a registered nurse presented the document to Ms. Guckin.

15. The informed consent document was materially deficient and misleading in several respects. For one, it did not include the term "experiment" or the phrase "clinical trial," thus masking the fact that this was a human subject experiment on a device still in its initial stage of development for the indicated use. In addition, the document did not accurately set forth the history of the prior experiments with the device, the risks associated with a malfunction of the device, or the alternatives available to human subjects.

16. Ms. Guckin did not fully understand the document because of the absence of the participation from qualified members of the clinical trial team, and because of what researchers call "the therapeutic misconception." Mr. and Ms. Guckin signed the document believing it was in her best therapeutic interest to undergo the procedure.

17. On September 12, 2000, Ms. Guckin underwent the procedure at Graduate Hospital. During the surgery, the device malfunctioned when it failed to automatically shut off when it reached a dangerous temperature, permanently damaging the sphincter muscle of Ms. Guckin.

18. After the surgery, Dr. Nagle willfully and falsely represented to Ms. Guckin that "everything went well," and that the surgery had been successful.

19. Immediately following surgery, Ms. Guckin began to experience excruciating pain and bleeding as a result of a gaping perianal wound caused by the device failure. Furthermore, she experienced an intensification of her earlier problems, including a total lack of sensation of or control over her bowel movements.

20. Dr. Nagle failed to treat the injuries suffered by Ms. Guckin in a prompt, candid, and professional manner; such failure caused additional and irreversible damage to Ms. Guckin.

21. Sixteen days after the original surgery, Dr. Nagle admitted Ms. Guckin to the hospital where she stayed for three weeks. During this time, Ms. Guckin underwent procedures involving the debridement of the necrotic tissue, causing her extreme pain and suffering.

22. Following the second surgery, Dr. Nagle finally admitted to Ms. Guckin that a mishap had in fact occurred in the initial procedure. She told Ms. Guckin, "I am not going to do this procedure again until I find out what happened."

23. Also during this period, an intern at the hospital, after treating Ms. Guckin, told her, "I hope you are seeking legal advice because your sphincter muscle had been almost completely destroyed." The Director of Surgery at Graduate Hospital, upon learning of the intern's comments to Ms. Guckin, tried to convince Ms. Guckin that the intern had been wrong and told her, "you are healing nicely." By information and belief, the intern was terminated by Graduate Hospital for telling Ms. Guckin the truth about what happened to her.

24. At some time during this period, Dr. Nagle finally admitted that the device, which was supposed to create scars in the sphincter and automatically shut down if it got too hot, failed to shut off properly. Dr. Nagle tried to excuse this malfunction by explaining that the reason for the malfunction in the device was that Ms. Guckin's "global tissue temperature was too high." Dr. Nagle knew this excuse was false and that the device simply failed to operate properly.

25. According to Curon, a computer controlling system in the device is supposed to modulate the area set for operation to a precise, desired temperature.

26. The informed consent document also states: "temperature of the thermal treatment [is regulated] with a computer controlled system."

27. As a result of the negligence, recklessness, and intentional misconduct of defendants, Ms. Guckin has little or no sphincter muscle and is completely dependent on diapers because of her total lack of control over her bowel movements. Accidents, which in the past occurred only occasionally, are now an everyday reality that she must suffer through. In addition, she suffers pain and discomfort and humiliation on a daily basis.

28. As a result of the physical injuries caused by the action and failures of defendants, Ms. Guckin has undergone severe emotional and psychological distress caused by the humiliation and fear of her present condition.

29. As a result of the physical injury caused by the initial procedure, Ms. Guckin has undergone and will undergo medical treatment to ease the pain and discomfort from which she suffers and will suffer in the future.

30. Ms. Guckin's quality of life, because of defendants' wrongful acts, is miserable.

31. 45 CFR '46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as Graduate Hospital.

32. These regulations require:

Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

...

Risks to subjects are reasonable in relation to anticipated benefits.

...

Selection of subjects is equitable.

...

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by '46.116.

...

Informed consent will be appropriately documented, in accordance with, and to the extent required by '46.117.

...

Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

...

Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

...

Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

33. As set forth above, defendants have violated these regulations to the great damage and detriment of Ms. Guckin.

FIRST CAUSE OF ACTION

NEGLIGENCE

34. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

35. Defendants, as set forth above, were negligent in that they failed to treat Ms. Guckin in accordance with the standards governing the medical and research professions, failed to conduct the clinical trial in a careful and professional manner, failed to treat Ms. Guckin properly once she suffered injury in the experiment, failed to abide by 45 C.F.R. §46 and other regulations and standards governing the conduct of clinical trials, and otherwise acted negligently as a matter of law.

36. As a direct and proximate result of defendants' actions, as set forth above, Ms. Guckin was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her internal system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss; and she has suffered a breach of her right to essential human dignity as a result of the

failure of defendants to conduct a clinical trial in accordance with standards governing human subject protection.

37. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which they may otherwise be entitled to recover.

38. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

SECOND CAUSE OF ACTION

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

39. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

40. As set forth above, the informed consent process engaging the defendants was materially deficient, misleading and contrary to the regulations and standards

41. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Eileen Guckin, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to internal system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss; and she has suffered a breach of her right to essential human dignity as a result of the failure of defendants to conduct a clinical trial in accordance with standards governing human subject protection.

42. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may

exceed amounts which plaintiff may otherwise be entitled to recover.

43. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

THIRD CAUSE OF ACTION

***INTENTIONAL AND NEGLIGENT INFLICTION
OF EMOTIONAL DISTRESS***

44. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

45. Defendants engaged in the conduct described above willfully, recklessly and/or negligently causing Eileen Guckin severe emotional distress.

46. As a direct and proximate result of defendants' actions, as set forth above, plaintiff Eileen Guckin was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her internal system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss; and she has suffered a breach of her right to essential human dignity as a result of the failure of defendants to conduct a clinical trial in accordance with standards governing human subject protection.

47. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

48. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of

Pennsylvania.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

FOURTH CAUSE OF ACTION

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

49. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

50. Defendants made the following intentional misrepresentations and committed common law fraud in:

- a. intentionally misrepresenting the nature and history of the clinical trial; and
- b. intentionally misrepresenting facts relating to the adverse event which occurred during the course of the clinical trial.

51. The intentional misrepresentations set forth above were done to induce plaintiff to participate in the clinical trial and in defendants' attempts to remedy the adverse results.

52. The misrepresentations set forth above were done with the knowledge that the misrepresentations were false when made.

53. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decision as to whether to participate.

54. As a direct and proximate result of defendants' actions, as set forth above, plaintiff Eileen Guckin was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her internal system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss, and she has suffered a breach of her essential human dignity.

55. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

56. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and

embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff has suffered severe emotional, psychological and personal injuries.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

**FIFTH CAUSE OF ACTION
STRICT LIABILITY IN TORT**

57. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

58. At all times relevant hereto, defendants were in the business of developing, testing, marketing, promoting and utilizing the Secca System.

59. At sometime prior to September 9, 2000, Curon tested, marketed, promoted and/or sold the Secca System utilized by Graduate Hospital during the surgery on Eileen Guckin.

60. Upon information and belief, the device utilized in surgery by Graduate Hospital was expected to, and did, reach the facility in the condition in which it was intended and/or sold by Curon.

61. At the time the Secca System was tested, marketed, promoted and/or sold for the use by Graduate Hospital on Eileen Guckin, the device was in a defective condition and unreasonably dangerous in at least the following particulars:

a. The device was defective and/or unreasonably dangerous when used under the conditions contained in the product information literature;

b. The device was not accompanied by adequate or explicit labeling;

c. The device contained inadequate labeling;

d. The device was not accompanied by adequate directions for its safe use;

e. The device was improperly marketed;

f. The device's advertising and promotional materials contained misrepresentations of material facts and/or failed to contain sufficient material facts necessary for physicians and/or consumers to make informed decisions regarding its selection and use;

g. The device's labeling contained misrepresentations of material fact and/or failed to contain sufficient material facts necessary for physicians and/or consumers to make informed decisions regarding its selection and use;

h. Information necessary for the Food and Drug administration to make informed judgments regarding the safety and efficacy of the device was withheld, improperly reported and/or insufficient;

i. The device was dangerous to one's health when used as recommended or suggested in the labeling, advertising and promotional materials promulgated to both the medical community and the plaintiff by the defendants;

j. The dangers associated with the use of the device exceeded the expectations of the average consumer; and

k. The device was over-promoted.

62. Curon placed the Secca System into the stream of commerce in a defective condition that was unreasonably dangerous to persons such as Eileen Guckin in that the device lacked adequate warnings and instructions about dangers that were known, or should have been known, by Curon.

63. As a direct and proximate result of the placement of the Secca System into the stream of commerce in a defective condition by Curon and its use by Dr. Nagle and Graduate Hospital, Eileen Guckin was deprived of the information necessary to decide whether or not to utilize the device and was injured by the device's failure to operate properly.

64. By reason of the wanton, willful and outrageous conduct of defendants, as aforesaid, plaintiff was caused to sustain severe emotional, psychological and personal injuries.

65. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which they may otherwise be entitled to recover.

66. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

SIXTH CAUSE OF ACTION NEGLIGENCE Eileen Guckin vs. IRB Defendants

67. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

68. The IRB defendants who approved the experiment had a duty to protect Eileen Guckin and other subjects from unethical research practices.

69. The IRB defendants were negligent in approving the design of the study, in approving the informed consent document, and in not monitoring appropriately the informed consent process and the conduct of the trial.

70. As a direct and proximate result of defendants' actions, as set forth above, Eileen Guckin was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her internal system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss; and she has suffered a breach of her right to essential human dignity.

71. As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past been and may in the future continue to be compelled to expend monies and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

72. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff has suffered severe emotional, psychological and personal injuries.

WHEREFORE, Eileen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

Stephen Guckin vs. All Defendants

73. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

74. As a result of the injuries sustained by Eileen Guckin, plaintiff Stephen Guckin has been and will continue to be deprived of the assistance, companionship, consortium and

society of his wife, all to his loss and detriment.

WHEREFORE, Stephen Guckin claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs of suit.

**SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY A Professional
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