

**Eileen Guckin and Stephen  
Guckin, 934 Herbert Street  
Philadelphia, PA  
19124 Plaintiffs, vs. Deborah Nagle,  
individually and as an Employee of  
Tenet Healthcare Corporation and  
Graduate Hospital, Inc. 1800  
Lombard Avenue Philadelphia, PA  
19146**

**and**

**Graduate Hospital, Inc. 1800  
Lombard Avenue Philadelphia, PA  
19146**

**and**

**Tenet Healthcare Corporation 3820  
State Street Santa Barbara, CA 93105**

**and**

**Curon Medical, Inc. 735 Palomar  
Avenue Sunnyvale, CA 94085**

**and**

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

**: COURT OF COMMON  
PLEAS PHILADELPHIA COUNTY  
: Term, 2002 Docket Number: 0014**

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**Defendant. :**

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## ***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. 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 100 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 Palo Alto 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 who complained that she had been experiencing episodes of fecal incontinence for many years. Accidents stemming from her inability to properly control her bowels, however 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 and was 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 urologist 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 and had proved its success.12. Dr. Nagle further represented the procedure was the best alternative for Ms. Guckin and that, even if unsuccessful, her condition would not worsen as a result of the procedure.13. In August of 2000, Dr. Nagle represented that Ms.

had qualified to be included in the study at Graduate Hospital and that she would receive \$300 for participating.<sup>14</sup> On August 18, 2000, Ms. Guckin was presented with a 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.<sup>15</sup> 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 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 risk of injury with a malfunction of the device, or the alternatives available to human subjects. Ms. Guckin did not fully understand the document because of the absence of the participation of qualified members of the clinical trial team, and because of what researchers call "therapeutic misconception." Mr. and Ms. Guckin signed the document believing that the procedure was in their best therapeutic interest to undergo the procedure.<sup>17</sup> 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, which permanently damaging the sphincter muscle of Ms. Guckin.<sup>18</sup> After the surgery, Dr. Nagle willfully and falsely represented to Ms. Guckin that "everything went well," and that the surgery had been successful.<sup>19</sup> 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 symptoms, including a total lack of sensation of or control over her bowel movements.<sup>20</sup> 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.<sup>21</sup> Two 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 debridement of the necrotic tissue, causing her extreme pain and suffering.<sup>22</sup> Following her second surgery, Dr. Nagle finally admitted to Ms. Guckin that a mishap had indeed occurred in the initial procedure. She told Ms. Guckin, "I am not going to do this procedure until I find out what happened."<sup>23</sup> Also during this period, an intern at the hospital, who spoke to 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 she had been wrong and told her, "you are healing nicely." By information and belief

was terminated by Graduate Hospital for telling Ms. Guckin the truth about what happened to her.<sup>24</sup> At some time during this period, Dr. Nagle finally admitted that the device was supposed to create scars in the sphincter and automatically shut down if it 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 would not operate properly.<sup>25</sup> According to Curon, a computer controlling system in the device was supposed to modulate the area set for operation to a precise, desired temperature. The informed consent document also states: "temperature of the thermal treatment [is] controlled with a computer controlled system."<sup>27</sup> As a result of the negligence, recklessness, and intentional misconduct of defendants, Ms. Guckin has little or no sphincter muscle control 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 a daily reality that she must suffer through. In addition, she suffers pain and discomfort and humiliation on a daily basis.<sup>28</sup> As a result of the physical injuries caused by the failures of defendants, Ms. Guckin has undergone severe emotional and psychological distress caused by the humiliation and fear of her present condition.<sup>29</sup> As a result of the physical injury caused by the initial procedure, Ms. Guckin has undergone and will continue to require medical treatment to ease the pain and discomfort from which she suffers and will suffer in the future.<sup>30</sup> Ms. Guckin's quality of life, because of defendants' wrongful acts, is miserable.<sup>31</sup> 45 CFR '46, part of the Code of Federal Regulations, establishes the standards for the United States with respect to the protection of human research subjects at institutions like Graduate Hospital.<sup>32</sup> 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 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 '46.117... 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, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of identifiable 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

economically or educationally disadvantaged, appropriate additional safeguards 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 detriment of Ms. Guckin.

### ***FIRST CAUSE OF ACTION NEGLIGENCE***

34. Plaintiffs incorporate by reference all other paragraphs of this complaint as set forth herein. 35. Defendants, as set forth above, were negligent in that they failed to protect Ms. Guckin in accordance with the standards governing the medical and research practice. Defendants failed to conduct the clinical trial in a careful and professional manner, failed to provide medical care to Ms. Guckin properly once she suffered injury in the experiment, failed to abide by 45 CFR 46.101 and other regulations and standards governing the conduct of clinical trials, and acted negligently as a matter of law. 36. As a direct and proximate result of defendants' negligent actions, as set forth above, Ms. Guckin was caused to sustain serious, disabling permanent personal and psychological injuries. She has in the past been required to continue to be required to submit to medical examinations; she sustained 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 be required to require medicines, medical care and treatment; she has in the past and may in the future be compelled to expend monies and incur obligations for such medical treatment; she has in the past suffered and may in the future continue to suffer aches, pains and mental anguish; she has in the past been and may in the future be disabled from performing her usual duties, occupations and avocations, all to her 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 the standards governing human subject protection. 37. As a direct and proximate result of defendants' negligent actions, as set forth above, plaintiffs have in the past been and may in the future be compelled to expend monies and incur obligations for Ms. Guckin's medical treatment; plaintiffs have also incurred and may hereafter continue to incur other expenses or losses which do or may exceed amounts which they may otherwise recover. 38. Plaintiff has sustained and makes claims for pain and suffering, loss of function, permanent physical, mental, dignitary and psychological injuries, humiliation, embarrassment, loss of life's pleasures, loss of earning capacity, and any and all

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 reasonable and allowable costs of suit.

***SECOND CAUSE OF ACTION INTENTIONAL ASSAULT AND BATTERY  
INFORMED CONSENT***

39. Plaintiffs incorporate by reference all other paragraphs of this complaint as set forth herein. 40. As set forth above, the informed consent process engaging the defendant was materially deficient, misleading and contrary to the regulations and standards, 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 physical 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; other psychological injuries, the full extent of which have yet to be determined; 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 pay 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 distress; she has in the past been and may in the future continue to be disabled from performing usual duties, occupations and avocations, all to her great detriment and loss; and she 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 pay 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 that may or may not be covered by insurance 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, personal and 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 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 pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs o

### ***THIRD CAUSE OF ACTION***

#### ***INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DI***

44. Plaintiffs incorporate by reference all other paragraphs of this complaint as i  
forth herein.45. Defendants engaged in the conduct described above willfully, re  
and/or negligently causing Eileen Guckin severe emotional distress.46. As a dir  
proximate result of defendants' actions, as set forth above, plaintiff Eileen Guck  
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of her right to essential human dignity as a result of the failure of defendants to  
clinical trial in accordance with standards governing human subject protection.4  
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for Ms. Guckin's medical care and treatment; plaintiffs have also incurred and n  
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plaintiff may otherwise be entitled to recover.48. Plaintiff has sustained and mai  
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law of the Commonwealth of Pennsylvania.**WHEREFORE**, Eileen Guckin clai  
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excess of One Million Dollars (\$1,000,000.00), delay damages pursuant to Pa. I

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 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 in the course of the clinical trial.

51. The intentional misrepresentations set forth above were done to induce plaintiffs to participate in the clinical trial and in defendants' attempts to remedy the adverse event. 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 in a direct and proximate result of defendants' actions, as set forth above, plaintiff 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 systems and 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 medical expenses; she has in the past been and may in the future continue to be disabled from performing usual duties, occupations and avocations, all to her great detriment and loss, and she 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 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 financial expenses or losses which do or may exceed amounts which plaintiff may 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 humiliation and embarrassment, loss of life's pleasures, loss of earning capacity 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 malicious misrepresentations as set forth above, plaintiff has suffered severe emotional, physical and personal injuries. **WHEREFORE**, Eileen Guckin claims of defendants, and 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 allowable costs of suit.

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

57. Plaintiffs incorporate by reference all other paragraphs of this complaint as set forth herein. 58. At all times relevant hereto, defendants were in the business of 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 by Graduate Hospital during the surgery on Eileen Guckin. 60. Upon information received, the device utilized in surgery by Graduate Hospital was expected to, and did, render plaintiff in a 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. 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 misrepresentation 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 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.

health when used as recommended or suggested in the labeling, advertising and materials promulgated to both the medical community and the plaintiff by the defendant. The dangers associated with the use of the device exceeded the expectations of a reasonable consumer; and the device was over-promoted.

62. Curon placed the Secca System into the stream of commerce in a defective condition which 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.<sup>63</sup> 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 Drexel University Graduate Hospital, Eileen Guckin was deprived of the information necessary to make an informed decision whether or not to utilize the device and was injured by the device's failure to operate properly.<sup>64</sup> By reason of the wanton, willful and outrageous conduct of defendants aforesaid, plaintiff was caused to sustain severe emotional, psychological and physical injuries.<sup>65</sup> As a direct and proximate result of defendants' actions, as set forth herein, plaintiffs have in the past been and may in the future continue to be compelled to undergo medical procedures and incur obligations for Ms. Guckin's medical care and treatment; plaintiffs also incurred and may hereafter continue to incur other financial expenses or losses which may exceed amounts which they may otherwise be entitled to recover.<sup>66</sup> Plaintiff sustains and makes claims for pain and suffering, loss of physical function, personal and 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 plaintiff 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 litigation.

#### **SIXTH CAUSE OF ACTION NEGLIGENCE Eileen Guckin vs. IRB Defendants**

67. Plaintiffs incorporate by reference all other paragraphs of this complaint as set forth herein.<sup>68</sup> The IRB defendants who approved the experiment had a duty to protect Eileen Guckin and other subjects from unethical research practices.<sup>69</sup> 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 progress of the trial.<sup>70</sup> As a direct and proximate result of defendants' actions, as set forth herein, plaintiffs have incurred and may hereafter continue to incur other financial expenses or losses which may exceed amounts which they may otherwise be entitled to recover.

Eileen Guckin was caused to sustain serious, disabling and permanent personal psychological injuries. She has in the past been required and may in the future be required to submit to medical examinations; she sustained other injuries to her immune system; she sustained other psychological injuries, the full extent of which have not been determined; she has in the past been required and may in the future continue to require 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 and mental anguish; she has in the past been and may in the future continue to be disabled in performing her usual duties, occupations and avocations, all to her great detriment and she has suffered a breach of her right to essential human dignity.<sup>71</sup> As a direct and proximate result of defendants' actions, as set forth above, plaintiffs have in the past 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 continue to incur other financial expenses or losses which do or may exceed amount a plaintiff may otherwise be entitled to recover.<sup>72</sup> Plaintiff has sustained and may continue to sustain 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 emotional, psychological and personal injuries. **WHEREFORE**, Eileen Guckin claims against 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. 237 and punitive damages and interest and allowable costs of suit.

***SEVENTH CAUSE OF ACTION LOSS OF CONSORTIUM Stephen Guckin  
Defendants***

73. Plaintiffs incorporate by reference all other paragraphs of this complaint as set forth herein.<sup>74</sup> 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 against defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Million Dollars (\$1,000,000.00), delay

pursuant to Pa. R.C.P. 238, punitive damages and interest and allowable costs o

**SHERMAN, SILVERSTEIN, KOEHLER  
PODOLSKY A Professional Corpora**

**Dated: JUNE 7, 2002**

By: \_\_\_\_\_  
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