**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

CIVIL ACTION NO.: 11-10204-MLW

ROBERT ZEMAN
and
JULIA ZEMAN,
Plaintiffs,
v.
ZIV WILLIAMS, M.D.,
EMAD ESKANDAR, M.D.,
INDIVIDUAL MEMBERS OF THE INSTITUTIONAL REVIEW BOARD: MELISSA FRUMIN, M.D., HINA ALAM, SARY F. ARANKI, M.D., RHONDA BENTLEY-LEWIS, M.D., SUSAN BURNSIDE, RICHARD D'AUGUSTA, ASHWIN DHARMADHIKARI, M.D., DAVID A. JONES, M.D., DEBORAH ECKER, ROBERT J. GLYNN., ELIZABETH L. HOHMANN, M.D., THOMAS KOLOKOTRONES, KEITH A. MARCOTTE, FRANCISCO MARTY, M.D., ELINOR A MODY, M.D., JOAN RILEY, ANDREW P. SELWYN, ARTHUR C. WALTMAN, M.D., SJIRK WESTRA, M.D. and SEAN R. WILSON, M.D.,
MEDTRONIC, INC.
and
NEUROLOGIX, INC.,
Defendants.

# PLAINTIFFS' AMENDED COMPLAINT

## Jurisdiction

Jurisdiction in is based on so-called diversity of citizenship pursuant to 28 U.S.C. § 1332, with the amount in controversy in excess of Seventy-Five Thousand ($75,000.00) Dollars.

## Venue

Venue is based upon 28 USC 1391(a)(2).

## The Parties

1. Plaintiff Robert Zeman ("Zeman") is an individual residing at 5142 Hollister Avenue, #195 Santa Barbara, California 93111, and is a citizen of the state of California.

2. Plaintiff Julia Zeman ("Mrs. Zeman") is an individual residing at 5142 Hollister Avenue, #195 Santa Barbara, California 93111, and is a citizen of the state of California.

3. At all times relevant to the Complaint, Plaintiffs Robert Zeman and Julia Zeman were married and residing together.

4. Defendant Ziv Williams, M.D. ("Dr. Williams"), is an individual and citizen of the Commonwealth of Massachusetts, with a principal place of business at 55 Fruit Street, Boston, Massachusetts 02114.

5. Defendant Emad Eskandar, M.D. ("Dr. Eskandar"), is an individual and citizen of the Commonwealth of Massachusetts, with a principal place of business at 55 Fruit Street, Boston, Massachusetts 02114.

6. At all times relevant to the Complaint, Drs. Williams and Eskandar were physicians licensed to practice medicine in the Commonwealth of Massachusetts.

7. At all times relevant to the Complaint, Drs. Williams and Eskandar each had a doctor-patient relationship with Zeman.

8. At all times relevant to the Complaint, Drs. Williams and Eskandar were each a "provider of health care" within the meaning of c. 231 Sec. 60B.

9. Defendants individual members of the Institutional Review Board ("IRB"): Melissa Frumin, M.D., Hina Alam, Sary F. Aranki, M.D., Rhonda Bentley-Lewis, M.D.,

Susan Burnside, Richard D'Augusta, Ashwin Dharmdhikari, M.D., David A. Jones, M.D., Deborah Ecker, Robert J. Glynn, Elizabeth L. Hohmann, M.D., Thomas Kolokotrones, Keith A. Marcotte, Francisco Marty, M.D., Elinor A Mody, M.D., Joan Riley, Andrew P. Selwin, Arthur C. Waltman, M.D., Sjirk Westra, M.D. and Sean R. Wilson, M.D. ("IRB Members"), are individuals who are members of the IRB which approved the experiment that is the subject of this Complaint. Each is believed to be a citizen of the Commonwealth of Massachusetts and/or a citizen of a state other than California.

10. Defendant Medtronic, Inc. ("Medtronic") is a Minnesota corporation with a principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432

11. Defendant Neurologix, Inc., ("Neurologix") is believed to be a Delaware Corporation with a principal address at One Bridge Plaza, Fort Lee, NJ 07024. Neurologix is believed to be a citizen of New Jersey and Delaware.

## FACTS COMMON TO ALL COUNTS

12. Plaintiff Zeman is a labor and employment attorney in Santa Barbara, California.

13. Plaintiff Zeman graduated from the University of the Pacific-McGeorge School of Law with honors in May 1990. Later, said plaintiff became the youngest branch managing shareholder in firm history with Littler, Mendelson, P.C. one of the nation's largest employment law firms.

14. Plaintiff Zeman is the father of three children. He married his second wife, Julia, in 2008.

15. In February 1996, at the age of 30, Plaintiff Zeman was diagnosed with Young On-Set Parkinson's Disease.

16. Parkinson's Disease ("Parkinson's") is a progressive neurodegenerative disorder characterized by the loss of dopaminergic neurons in the brain and resulting tremors, shaking, slow movement, and muscle stiffness and rigidity.

17. By November 2008, the therapeutic effect of the medications Plaintiff Zeman was taking to control the Parkinson's symptoms was wearing off faster and faster. Thus, he was experiencing more "off-time" during which his symptoms were worse. These symptoms were primarily slowness of movement, rigidity, and "freezing" or the inability to walk or move for seconds or longer.

18. Plaintiff Zeman began researching various treatment options, including Deep Brain Stimulation (DBS). DBS is one of the latest FDA approved treatments for Parkinson's. It uses a Medtronic pulse generator similar to a pacemaker implanted close to the clavicle area wired to the sub-thalamic nucleus area of the brain (one on each side). Said plaintiff declined this treatment for many reasons, including the need for multiple surgeries and because he was told it was a temporary fix involving a lot of weekly adjustments.

19. Plaintiff Zeman then learned about a clinical trial using Gene Transfer on both sides of the brain in the sub-thalamic nucleus ("STN") conducted at Mass General.

20. Gene Transfer, sometimes mistakenly called Gene Therapy, is an experimental procedure whereby specific genes are directed to target a specific region of the body using a viral vector, in this case the adeno-associated virus ("AAV") , on the theory that the genes would express themselves, creating more healthy genes in that part of the body where defective genes had resided.

21. The clinical trial was titled: “Safety and Efficacy Study Evaluating Glutamic Acid Decarboxylase Gene Transfer of Subthalamic Nuclei in Subjects with Advanced Parkinson’s Disease” (“the experiment”); the design of the experiment was to deliver genes directly into both sides of the brain in the hope they would produce an enzyme called Glutanic Acid Decarboxylase, which in turn would result in an increased production of gamma-aminobutyric acid (“GABA”), a neurotransmitter in short supply in the brains of Parkinson’s patients.

22. The Principal Investigator (“PI”) or designer of the experiment was originally Defendant Dr. Eskandar and later a Dr. Alice Flaherty.

23. The design of the experiment and the Informed Consent Forms to be given to potential human subjects were approved by the individual members of the IRB, who also were charged with the responsibility of ensuring the informed consent process was conducted consistent with applicable federal regulations and that the subjects were protected and were adequately informed as to their care and treatment.

24. The experiment was a single blind placebo study, meaning that half the subjects would undergo a “sham surgery” where no agent was delivered though a partial hole surgically made in the subject’s skull, while the other half would receive the study agent in both sides of the brain. The neurosurgeon and the PI were not blinded and knew whether the subject was receiving the study agent or a placebo.

25. The listed Sponsor of the experiment was Defendant Neurologix. One of the largest investors in Defendant Neurologix was Medtronic, principally because it hoped to market devices used in the experiment; it also used the experiment to test its Acute Brain Infusion Delivery System (“ABID System”), a device not yet approved by

the FDA, which Medtronic hoped to bring to market. The ABID System was to be used to deliver the genes directly into the brains of the human subjects.

26. The PI and the Sponsors chose Defendant Dr. Williams, a Harvard University neurosurgeon, to conduct the surgery using the ABID System.

27. Together, the Sponsor (i.e. Defendant Neurologix), Medtronic, the PIs (i.e. Defendant Dr. Eskandar and later Dr. Flaherty), the Defendant members of the IRB, and Defendant Dr. Williams formed the Research Enterprise for the experiment.

28. At all times, the defendants, and each of them respectively, jointly and severally, were charged with the professional responsibility of conducting an ethical experiment where risks did not greatly exceed benefits, of determining the universe of harm through proper preclinical animal studies, of properly conducting the informed consent process, of rendering proper care and treatment to Plaintiff Zeman, of properly and carefully designing and administering the experiment's protocol in a careful and prudent fashion, of assuring that proper care and attention were provided during all periods of time during which he remained under defendants' care and treatment, and of candidly and honestly advising him of the results and consequences of the experiment.

29. All the parties in the Research Enterprise knew that the AAV carried genes, or what the Informed Consent Form called the "study agent," which had to be delivered in both sides of the brain or else the human subject could be left seriously debilitated. They knew this because, when the study was first proposed to the Recombinant DNA Advisory Committee ("the RAC"), the federal government body designated to oversee all Gene Transfer experiments, a member of the RAC warned that treatment in only one side of the brain was "handicapping."

30. Prior to enrolling in the experiment, Plaintiff Zeman was given an Informed Consent Form, which, under the federal regulations governing the conduct of human subject research, was supposed to, among other things, describe the known risks of participating in the experiment. A copy of the Informed Consent Form given to said plaintiff prior to his participation is attached as Exhibit "A."

31. On or about November17, 2008, for a total of approximately five minutes, Defendant Dr. Eskandar discussed with Plaintiff Zeman the content of the more than twenty page Informed Consent Form describing the complicated Gene Transfer experiment. No subject advocate was provided.

32. This Informed Consent Form did not mention the risk that the study agent might not be delivered into both sides of the brain, that the catheter in the ABID System might be "misplaced or incorrectly placed", that a double dose of the study agent might result from such improper placement, and that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side.

33. Also, the Informed Consent Form did not mention that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent.

34. In addition, the Consent Form and the limited discussions with Defendant Dr. Eskandar were materially misleading and deceptive in several other respects: These include:

a. The procedure was not described as “a human experiment” and instead was represented to be therapeutic in nature. The risk of toxic effects of the virus vector was understated.

b. There was no warning that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

c. Gene Transfer was represented as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world’s premier Gene Transfer scientists.

d. The procedure was represented as safe and effective for the treatment of Parkinson’s;

e. There was no disclosure with respect to prior animal studies.

f. The financial conflicts of interest inherent in the experiment were not disclosed.

g. No subject advocate was provided to the potential human subjects.

35. Relying on the representations made by the members of the Research Enterprise, Plaintiff Zeman signed the Informed Consent Form.

36. On December 4, 2008, Plaintiff Zeman thus became the first human subject to have what was supposed to be bilateral Gene Transfer in the brain as a potential cure or therapy for Parkinson’s.

37. Defendant Dr. Williams conducted the surgery at Massachusetts General Hospital with representatives of Defendant Neurologix and Medtronic in the operating room.

38. Rather than placing the catheter in the ABID System into each side of Plaintiff Zeman's brain, in accordance with the experiment's design and the RAC's warnings, the two catheters were both placed in the left side of his brain delivering a double dose of the study agent only on the left side of the brain.

39. During the surgery, a lateral skull film was taken to determine the location of the catheters. Then shortly after the surgery, but before the catheters were removed, a CT scan was performed to determine, among other things, where the catheters had been placed in the subthalamic portions of the brain. The CT scan clearly showed that the right catheter was misplaced into the left STN, although the radiologist mistakenly refers to each catheter as a "deep brain stimulator electrode." A copy of the CT scan report dated December 4, 2008, is attached as Exhibit "B."

40. After the surgery was completed, all the parties in the Research Enterprise had ethical, legal and regulatory obligations to advise Plaintiff Zeman what went wrong; instead, they willfully chose to attempt to cover up what they knew to be a serious and catastrophic mistake.

41. Plaintiff Zeman was first repeatedly told that the surgery went well. This was not true. The surgery did not go well as the CT scan showed.

42. Approximately two weeks after the surgery, Plaintiff Zeman met with Defendant Dr. Williams who "unblinded" him and told him he had received the study agent. Defendant Dr. Williams advised, however, that said plaintiff only received the study agent on one side, the left, because there was "a kink" in the right side catheter. The doctor advised they did not know where the catheter ended up on the right side but that it most likely did not end up in the sub-thalamic region of the brain, though he

advised there was a small chance of the genes going into the right side subthalamic nucleus where they were supposed to go. This was not true. The CT scan showed both catheters terminated "within the left subthalamic region," meaning that a double dose of the study agent was delivered on the left side of the brain.

43. Defendant Dr. Williams further advised Plaintiff Zeman that if he liked the results on the left side of the brain he would be able to have the surgery done again on the right side at the one-year mark. This was not true either.

44. On December 7, 2008, Plaintiff Zeman returned to Santa Barbara.

45. Three days later, on December 10, 2008, Plaintiff Zeman receive a call from Defendant Dr. Williams, asking him to go immediately to Cottage Hospital in Santa Barbara to get an MRI that he had just scheduled. He was told that it was just a routine follow-up. The MRI report from Cottage revealed there was bleeding in the brain as a result of the surgery but Plaintiff Zeman was not advised of the results.

46. In March 2009, Plaintiff Zeman and his wife traveled back to Boston for a scheduled follow up and were advised, without explanation, that Defendant Dr. Eskandar replaced Dr. Williams who had performed the surgery and that Dr. Flaherty had also replaced the PI. Plaintiff Zeman was advised to follow up with Dr. Eskandar and that there was no need to speak to Dr. Williams again.

47. At this visit, Plaintiff Zeman was presented with another Informed Consent Form because, he was told, of the change in the PI. This form, to his eye, appeared identical to the one he had signed prior to the surgery except the name of the PI was changed. A copy of a portion of this second Informed Consent Form is attached as Exhibit "C."

48. Without explanation, Plaintiff Zeman was asked to sign this second form, not realizing that inserted in the document under "risks" was the sentence: "There is also a risk that the catheter (the tube used to inject your brain) used in the surgery might be misplaced or incorrectly placed." Since Zeman had already had the Gene Transfer, the only conceivable reason said plaintiff was given this form to sign was so the members of the Research Enterprise could claim they had warned him of the risk of precisely what happened to him during the surgery when, of course, they had not

49. Upon returning to Santa Barbara, Plaintiff Zeman's dyskinesia began increasing and became more and more debilitating.

50. Six months after the surgery, Plaintiff Zeman returned to Boston for a follow up visit where he underwent an MRI, PET scans, a neuro-psychological exam, blood work, urine analysis, and an EKG. He was advised there was some improvement in motor skills while in the off stage, twelve hours with no medication, but only on the right side which was controlled by the left side of the brain.

51. Plaintiff Zeman was advised that the PET scan results would clearly indicate the improvement, if any, in either of his STNs. He was further advised that the PET scan results would be completed in approximately two weeks and he was given a phone number to a Dr. Andrew Feigin in New York who was the one interpreting the PET scans.

52. When Plaintiff Zeman called the number, Dr. Feigin remarked: "So you're the guy who got the double dose of the gene on one side?" This was the first time said plaintiff learned he had received a double dose of the study agent into his left STN although he did yet know how it had happened.

53. Plaintiff Zeman then called Dr. Flaherty, the second PI. When he asked her if he had received a double dose, she responded that she knew there had been "some discussion" about that possibility but because she wasn't in the operating room she did not know and that he should discuss it with Dr. Williams.

54. Plaintiff Zeman had been the first subject in the high profile experiment she was now conducting; the Informed Consent Form had been changed after his surgery. Dr. Flaherty had an ethical and legal obligation to find out and know what had occurred during surgery and to inform Zeman with respect to what had occurred. This she failed to do.

55. When Plaintiff Zeman called Defendant Dr. Williams and asked about the possibility of a "double dose," Dr. Williams replied that their best estimate was that he did not receive an extra dose because they believed the right catheter had malfunctioned. Nothing in the medical records provided to Plaintiff Zeman corroborates the claim that the right catheter malfunctioned. Defendant Dr. Williams did not say that the right catheter ended up in the left STN, nor did he mention any hemorrhaging in the brain during surgery. Defendant Dr. Williams assured Plaintiff Zeman that if he did get a second dose, it was completely safe and that he could still have the right side done. Defendant Dr. Williams then apologized for not being clearer about the "possibility" of a double dose being administered.

56. Plaintiff Zeman then requested his medical records from Massachusetts General Hospital via email and was told they were "confidential study records" and he could only see them after the entire study was over, but if his doctor needed them for treatment, the doctor could ask for them.

57. In July 2009, Plaintiff Zeman's physician, Dr. James Sutton, requested the medical records in an effort to determine why Plaintiff Zeman was deteriorating so rapidly, and how he could have received a double dose. Massachusetts General Hospital provided a limited number of records including the CT scan revealing that the right side catheter had mistakenly terminated in the left sub-thalamic nucleus where the left catheter had been placed.

58. In a later conversation with Dr. Flaherty, she questioned how Plaintiff Zeman had gotten the CT scan, telling him the VP of the Sponsor was irate over his obtaining a copy of the records.

59. Dr. Sutton advised Plaintiff Zeman to get the right STN done as soon as possible as this was his best hope of balancing out his body because of the severe dyskinesia on the right side.

60. From October 2009 to January 2010, Plaintiff Zeman received numerous emails from the members of the Research Enterprise extolling the benefits of the second surgery and advising that it was approved by the FDA, and by Defendants the IRB members, the Sponsor, and Massachusetts General.

61. In January 2010, Plaintiff Zeman was advised he had developed a "slight" build-up of anti-bodies because of the mutated AAV virus, the Gene Transfer vector used to carry the genes into the cells in STN. The risk was that if he had the second surgery, he might have such a strong immune reaction to the vector that it could cause inflammation in the brain, encephalitis, and/or death.

62. As a result of the infusion of a double dose of the study agent on only one side of the brain, Plaintiff Zeman has suffered and will continue to suffer severe and debilitating "handicapping" injuries.

63. Plaintiff Zeman has forever lost the possibility of having an infusion on the right side of his brain or of ever correcting the dose imbalance.

64. The administration of the double dose to the right STN as aforesaid and the resulting significant and persistent disability constituted a Serious Adverse Event ("SAE") pursuant to the protocol established by the IRB for the subject experiment. Yet Defendant Dr. Eskandar failed to report the SAE to the Sponsor as required by said protocol.

65. The alleged aforementioned "kink" in the ABID constituted an Adverse Event under that protocol, yet Defendant Dr. Eskandar failed to report the Adverse Event to the Sponsor as required by said protocol.

66. On June 22, 2010, Defendant Neurologix issued a press release about the subject Gene Transfer experiment in which it claimed that there were no serious adverse events related to the gene therapy or associated surgical procedures. This was not true.

## COUNT I
## NEGLIGENCE VS. DR. ZIV WILLIAMS

67. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

68. At all times relevant to the Complaint, defendant Dr. Williams was a neurosurgeon engaged in the study of Gene Transfer.

69. At all times relevant to the Complaint, Defendant Dr. Williams owed to Plaintiff Zeman the standard of care and skill of the average qualified member of the medical profession practicing the specialty practiced by said defendant.

70. Defendant Dr. Williams breached that standard of care in regard to Plaintiff Zeman by his:

a. failure to take reasonable steps to ensure that a proper dosage of the study agent was delivered to the SNT on both the left and right sides of the brain;

b. Failing to conduct standard brain mapping on the right side of Plaintiff Zeman's brain, prior to infusion of the study agent from the right-side catheter;

c. Failing to place the ABID right-side catheter in such a position that the study agent within such catheter would be infused into the right-side SNT;

d. Failing to perform a CT scan after insertion of the ABID but prior to infusion of the study agent in order to ensure proper placement of the right-side catheter;

e. failing to properly and adequately treat and care for his condition;

f. caring for plaintiff Zeman in a negligent and improper manner;

g. failing to properly monitor his condition both prior to and subsequent to the delivery of the experiment's investigational drugs;

h. failing to properly and timely observe, discover, diagnose, treat and care for his condition;

i. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the community;

j. failing to utilize the ABID System properly.

71. As a direct and proximate result of the careless, negligent and reckless conduct of Defendant Williams as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

72. Also, the careless, negligent and reckless conduct of Defendant Williams as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Ziv Williams, M.D. in a sum to be adjudged by a jury, plus interest and costs.

## COUNT II
## LACK OF INFORMED CONSENT VS. DR. ZIV WILLIAMS

73. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

74. On or about December 4, 2008, average members of the medical profession practicing Dr. Williams' specialty knew or should have known of the risks, potential consequences and alternatives to Defendant Dr. Williams' choice of treatment of the Plaintiff Zeman.

75. On or about December 4, 2008, Defendant Dr. Williams knew or should have known of the risks, potential consequences and alternatives to Defendant Dr. Williams' choice of treatment of the Plaintiff Zeman.

76. On and before December 4, 2008, Defendant Dr. Williams failed to inform Plaintiff Zeman of the alternatives and risks and potential consequences of said defendant's choice of treatment of the plaintiff, including but not limited to his:

a. failure to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failure to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failure to disclose that a double dose of the study agent might result from such improper placement;

d. failure to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failure to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failure to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature;

g. failure to adequately disclose the risk of toxic effects of the virus vector;

h. failure to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania;

i. representing Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists;

j. representing that the procedure was safe and effective for the treatment of Parkinson's;

k. failure to disclose the results of prior animal studies;

l. failure to disclose the financial conflicts of interest inherent in the experiment were not disclosed;

m. failure to properly conduct the informed consent process;

77. If Defendant Dr. Williams had informed Plaintiff Zeman of the alternatives to and risks and potential consequences of Defendant Dr. Williams' choice of treatment, neither said plaintiff nor a reasonable man in his position would have elected that choice of treatment.

78. The alternatives to and risks and potential consequences of the Defendant Dr. Williams' choice of treatment were material to a decision by Plaintiff Zeman and a reasonable person in his position as to whether to undergo that treatment.

79. As a direct and proximate result of Defendant Dr. Williams' failure to inform Plaintiff Zeman as aforesaid, Plaintiff Zeman consented to Dr. Williams' treatment, and was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

80. Also, Defendant Dr. Williams' failure to inform Plaintiff Zeman as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Ziv Williams, M.D. in a sum to be adjudged by a jury, plus interest and costs.

## COUNT III
## BATTERY VS. DR. ZIV WILLIAMS

81. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

82. Plaintiff Zeman consented to Dr. Williams performing a procedure in which one dose of study agent would be infused into the SNT on each side of the brain.

83. Defendant Dr. Williams instead caused the left-side SNT to be infused with two doses of study agent.

84. The above-referenced infusion of the left-sided SNT with a second dose of the study agent was an unpermitted touching of the left-sided SNT of Plaintiff Zeman's brain, and constitutes a battery committed by said defendant.

85. As a direct and proximate result of Defendant Dr. Williams' battery as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

86. Also, Defendant Dr. Williams' commission of a battery upon Plaintiff Zeman as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant

Ziv Williams, M.D. in a sum to be adjudged by a jury, plus interest and costs

**COUNT IV**
**INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS vs. DR. ZIV WILLIAMS**

87. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

88. Defendant Dr. Williams' conduct in regard to Plaintiff Zeman was extreme and outrageous in that he:

a. lied to said Plaintiff when he represented to him that a "kink" in the right-sided catheter probably caused it to fail to discharge a dose of study material;

b. compromised Plaintiff Zeman's ability to provide his treating doctor in his hometown of Santa Barbara, California an accurate medical history by falsely stating that said plaintiff had in all probability received a single dosage;

c. compromised Plaintiff Zeman's ability to provide his treating doctor in his hometown of Santa Barbara, California an accurate medical history by falsely stating that it was unknown where in the brain, if anywhere, the study agent from the right-side catheter went, when Defendant Williams knew from the aforementioned CT scans that in all probability the dose from said catheter ended up in the left-side SNT;

d. lied to Plaintiff Zeman when he told him that, even if he had received a double dose in the left-side SNT, it was completely safe;

e. communicated to Plaintiff Zeman the above lies and false representations in an effort to cover up his own wrongdoing and/or downplay the

effects of same, and in so doing willingly sacrificed the patient's ability to provide his own treating doctors in Santa Barbara with an accurate medical history.

89. The above referenced extreme and outrageous conduct of Defendant Dr. Williams caused Plaintiff Zeman to experience severe emotional distress of such a nature that no reasonable person could be expected to endure it.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Ziv Williams, M.D. in a sum to be adjudged by a jury, plus interest and costs.

**COUNT V**
**DECEIT/INTENTIONAL MISREPRESENTATION/FRAUD IN THE INDUCEMENT/BREACH OF FIDUCIARY DUTY VS. DR. ZIV WILLIAMS**

90. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

91. In the circumstances as set forth above, and in the context of the doctor-patient relationship, Defendant Williams owed Plaintiff Zeman a fiduciary duty. As such, Defendant Williams had an obligation to bring to Plaintiff Zeman's attention material facts bearing on the risks of the experiment.

92. On December 4, 2008, prior to infusion of the study agent on December 4, 2008, at Massachusetts General Hospital, Defendant Williams made the following intentional misrepresentations of material fact regarding the risks of the experiment for Plaintiff Zeman by or through his:

a. failure to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failure to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failure to disclose that a double dose of the study agent might result from such improper placement;

d. failure to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failure to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failure to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature.

g. failure to adequately disclose the risk of toxic effects of the virus vector;

h. failure to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. representing Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists.

j. representing that the procedure was safe and effective for the treatment of Parkinson's;

k. failure to disclose the results of prior animal studies.

l. failure to disclose the financial conflicts of interest inherent in the experiment were not disclosed.

m. failure to properly conduct the informed consent process;

93. Plaintiff Zeman reasonably relied on one or more of the above-referenced misrepresentations in making a determination that he would participate in the subject experiment.

94. Had Defendant Williams not made the above-reference misrepresentations, Plaintiff Zeman would not have participated in the experiment, nor would a reasonable man in his position.

95. The above misrepresentations constitute intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by defendant Williams.

96. As a direct and proximate result of the intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by defendant Williams as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

97. As a direct and proximate result of the intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by defendant Williams as aforesaid, Plaintiff Zeman suffered the reduction or elimination of his chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Ziv Williams, M.D. in a sum to be adjudged by a jury, plus interest and costs.

## COUNT VI
## LACK OF INFORMED CONSENT
## VS. DR. EMAD ESKANDAR

98. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

99. At all times relevant to the Complaint, Defendant Dr. Eskandar was a neurosurgeon engaged in the study of Gene Transfer.

100. In November, 2008 through and including December 4, 2008, average members of the medical profession practicing Dr. Eskandar's specialty knew or should have known of the risks, potential consequences and alternatives to the Gene Transfer experiment.

101. In November, 2008 through and including December 4, 2008, Defendant Dr. Eskandar knew or should have known of the risks, potential consequences and alternatives to the Gene Transfer experiment.

102. On November 17, 2008, Defendant Dr. Eskandar, in the course of providing information about the experiment to Plaintiff Zeman, failed to inform him of the alternatives and risks and potential consequences of said defendant's choice of treatment of the plaintiff, including but not limited to his:

a. failure to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failure to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failure to disclose that a double dose of the study agent might result from such improper placement;

d. failure to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failure to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failure to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature.

g. failure to adequately disclose the risk of toxic effects of the virus vector;

h. failure to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. representing Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists.

j. representing that the procedure was safe and effective for the treatment of Parkinson's;

k. failure to disclose the results of prior animal studies;

l. failure to disclose the financial conflicts of interest inherent in the experiment were not disclosed.

m. failure to properly conduct the informed consent process;

103. If Defendant Dr. Eskandar had informed Plaintiff Zeman of the alternatives to and risks and potential consequences of the experiment, neither said plaintiff nor a reasonable man in his position would have elected that choice of treatment.

104. The alternatives to and risks and potential consequences of the experiment were material to a decision by Plaintiff Zeman and a reasonable person in his position as to whether to undergo that treatment.

105. As a direct and proximate result of Defendant Dr. Eskandar's failure to inform Plaintiff Zeman as aforesaid, Plaintiff Zeman consented to the experiment, and was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

106. Also, Defendant Dr. Eskandar's failure to inform Plaintiff Zeman as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Emad Eskandar, M.D. in a sum to be adjudged by a jury, plus interest and costs.

## COUNT VII
## NEGLIGENCE VS. DR. EMAD ESKANDAR

107. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

108. Prior to December 4, 2008, Defendant Dr. Eskandar engaged in the drafting of and gave approval for a protocol for the conduct of the experiment, including an Informed Consent document a copy of which is attached as Exhibit A.

109. As PI, and/or as Plaintiff Zeman's doctor, Defendant Eskandar had a duty to draft and approve the protocol, including the Informed Consent document, with due care for the safety of experimental subjects such as Plaintiff Zeman.

110. At the time Defendant Dr. Eskandar engaged in the drafting of and gave approval for the aforementioned Informed Consent document, he knew or should have

known that said document did not adequately and reasonably present the alternatives to and risks and potential consequences of the experiment, in that said document:

a. failed to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failed to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failed to disclose that a double dose of the study agent might result from such improper placement;

d. failed to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failed to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failed to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature.

g. failed to adequately disclose the risk of toxic effects of the virus vector;

h. failed to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. represented Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists;

j. represented that the procedure was safe and effective for the treatment of Parkinson's;

k. failed to disclose the results of prior animal studies;

l. failed to disclose the financial conflicts of interest inherent in the experiment were not disclosed;

111. As a direct and proximate result of the careless, negligent and reckless conduct of Defendant Dr. Eskandar as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

112. Also, the careless, negligent and reckless conduct of Defendant Dr. Eskandar as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, plaintiff Robert Zeman demands judgment against defendant Emad Eskandar, M.D. in a sum to be adjudged by a jury, plus interest and costs.

## COUNT VIII
## INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS VS. DR. EMAD ESKANDAR

113. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

114. Defendant Dr. Eskandar's conduct in regard to Plaintiff Zeman was extreme and outrageous in that he:

a. failed to inform Plaintiff Zeman that the basis for his having replaced Dr. Williams in his role as provider of follow-up care for Plaintiff Zeman was his negligently performing the infusion of study agent as aforesaid;

b. misrepresented to Plaintiff Zeman that he had to sign a new Informed Consent document (Exhibit C) due to said defendant replacing Defendant Dr. Williams as aforesaid, when the true reason was that a clause had been added to warn against the precise risk that had eventuated as above-mentioned – the risk of the incorrect placement or misplacement of a catheter;

c. compromised Plaintiff Zeman's ability to provide his treating doctor in his hometown of Santa Barbara, California an accurate medical history by failing to inform him that he had received a double dose of the study agent in the left side of his brain, and no dose in the right side of the brain;

d. made the above lies, omissions and dirty trick in an effort to cover up the fact that a Serious Adverse Event and/or an Adverse Event had occurred in the conduct of the experiment, as well as in an attempt to provide a fraudulent defense to a malpractice claim against members of the Research Enterprise, and in so doing willingly sacrificed the patient's ability to provide his own treating doctors in Santa Barbara with an accurate medical history.

115. The above referenced extreme and outrageous conduct of Defendant Dr. Eskandar caused Plaintiff Zeman to experience severe emotional distress of such a nature that no reasonable person could be expected to endure it.

**WHEREFORE**, Plaintiff Robert Zeman demands judgment against defendant Emad Eskandar, M.D. in a sum to be adjudged by a jury, plus interest and costs.

**COUNT IX**
**DECEIT/INTENTIONAL MISREPRESENTATION/FRAUD IN THE INDUCEMENT/BREACH OF FIDUCIARY DUTY VS. DR. EMAD ESKANDAR**

116. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

117. In the circumstances as set forth above, and in the context of the doctor-patient relationship, Defendant Eskandar owed Plaintiff Zeman a fiduciary duty. As such, Defendant Eskandar had an obligation to bring to Plaintiff Zeman's attention material facts bearing on the risks of the experiment.

118. On November 17, 2008, at Massachusetts General Hospital, Defendant Dr. Eskandar, in the course of providing information about the experiment to Plaintiff Zeman, made the following intentional misrepresentations of material fact regarding the risks of the experiment for Plaintiff Zeman by or through his:

a. failure to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failure to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failure to disclose that a double dose of the study agent might result from such improper placement;

d. failure to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failure to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failure to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature.

g. failure to adequately disclose the risk of toxic effects of the virus vector;

h. failure to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. representing Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists.

j. representing that the procedure was safe and effective for the treatment of Parkinson's;

k. failure to disclose the results of prior animal studies;

l. failure to disclose the financial conflicts of interest inherent in the experiment were not disclosed;

m. failure to properly conduct the informed consent process;

119. Plaintiff Zeman reasonably relied on one or more of the above-referenced misrepresentations in making a determination that he would participate in the subject experiment.

120. Had Defendant Dr. Eskandar not made the above-reference misrepresentations, Plaintiff Zeman would not have participated in the experiment.

121. The above misrepresentations constitute intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by Defendant Dr. Eskandar.

122. As a direct and proximate result of the intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by Defendant Eskandar as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

123. As a direct and proximate result of the intentional misrepresentation, fraud in the inducement, deceit, and breach of fiduciary duty by Defendant Dr. Eskandar as aforesaid, Plaintiff Zeman suffered the reduction or elimination of his chance at achieving a more favorable medical outcome.

**WHEREFORE**, Plaintiff Robert Zeman demands judgment against Defendant Emad Eskandar, M.D. in a sum to be adjudged by a jury, plus interest and costs

## COUNT X
## NEGLIGENCE vs. IRB MEMBERS

124. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

125. Prior to December 4, 2008, the IRB Members engaged in the drafting of and gave approval for a protocol for the conduct of the experiment, including an Informed Consent document a copy of which is attached as Exhibit A.

126. On information and belief, some of the IRB Members are “providers of health care” as defined in c. 231 sec. 60B, and some are not.

127. As members of the IRB, the IRB Members had a duty to draft and approve the protocol, including the Informed Consent document, with due care for the safety of experimental subjects such as Plaintiff Zeman.

128. At the time the IRB Members engaged in the drafting of and gave approval for the aforementioned Informed Consent document, each of said defendants knew or should have known that said document did not adequately and reasonably present the alternatives to and risks and potential consequences of the experiment, in that said document:

a. failed to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failed to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failed to disclose that a double dose of the study agent might result from such improper placement;

d. failed to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failed to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failed to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature;

g. failed to adequately disclose the risk of toxic effects of the virus vector;

h. failed to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. represented Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists;

j. represented that the procedure was safe and effective for the treatment of Parkinson's;

k. failed to disclose the results of prior animal studies;

l. failed to disclose the financial conflicts of interest inherent in the experiment were not disclosed;

129. As a direct and proximate result of the careless, negligent and reckless conduct of the IRB Members as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

130. Also, the careless, negligent and reckless conduct of the IRB Members as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, Plaintiff Robert Zeman demands judgment against the individual IRB Members Defendants Melissa Frumin, M.D., Hina Alam, Sary F. Aranki, M.D., Rhonda Bentley-Lewis, M.D., Susan Burnside, Richard D'Augusta, Ashwin Dharmdhikari, M.D., David A. Jones, M.D., Deborah Ecker, Robert J. Glynn, Elizabeth L.

Hohmann, M.D., Thomas Kolokotrones, Keith A. Marcotte, Francisco Marty, M.D., Elinor A Mody, M.D., Joan Riley, Andrew P. Selwin, Arthur C. Waltman, M.D., Sjirk Westra, M.D. and Sean R. Wilson, M.D in a sum to be adjudged by a jury, plus interest and costs.

**COUNT XI**
**NEGLIGENCE VS. NEUROLOGIX, INC.**

131. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

132. Prior to December 4, 2008, Defendant Neurologix, as Sponsor of the experiment, engaged in the drafting of and gave approval for a protocol for the conduct of the experiment, including an Informed Consent document a copy of which is attached as Exhibit A.

133. Defendant Neurologix is not a provider of health care as defined in c. 231 sec. 60B.

134. As Sponsor of the experiment, Defendant Neurologix had a duty to draft and approve the protocol, including the Informed Consent document, with due care for the safety of experimental subjects such as Plaintiff Zeman.

135. At the time Defendant Neurologix engaged in the drafting of and gave approval for the aforementioned Informed Consent document, said defendant knew or should have known that said document did not adequately and reasonably present the alternatives to and risks and potential consequences of the experiment, in that said document:

a. failed to disclose the risk that the study agent might not be delivered into both sides of the brain;

b. failed to disclose that the catheters in the ABID System might be "misplaced or incorrectly placed";

c. failed to disclose that a double dose of the study agent might result from such improper placement;

d. failed to disclose that there was a risk of "handicapping" from either a double dose on one side, or from a single dose on one side and no dose on the other side;

e. failed to disclose that there was no radiologic or other procedure in the protocol designed to reliably confirm proper placement of the ABID catheters prior to infusion of the study agent;

f. failed to describe the procedure as "a human experiment" and instead was represented to be therapeutic in nature;

g. failed to adequately disclose the risk of toxic effects of the virus vector;

h. failed to disclose that a prior gene therapy experiment had resulted in the death of an 18-year-old volunteer at the University of Pennsylvania.

i. represented Gene Transfer as a proven therapy, a mere delivery device, and not an unproven and high-risk procedure with consequences unknown to even the world's premier Gene Transfer scientists. [Page 1 of 22 talks about gene transfer being new, page 2 talks about it being experimental. True that risks underplayed.];

j. represented that the procedure was safe and effective for the treatment of Parkinson's;

k. failed to disclose the results of prior animal studies;

l. failed to disclose the financial conflicts of interest inherent in the experiment were not disclosed;

136. As a direct and proximate result of the careless, negligent and reckless conduct of Defendant Neurologix as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

137. Also, the careless, negligent and reckless conduct of Defendant Neurologix as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, Paintiff Robert Zeman demands judgment against Defendant Neurologix, Inc.in the sum of Fifteen Million ($15,000,000.00) Dollars, plus interest and costs.

## COUNT XII
## NEGLIGENCE AGAINST MEDTRONIC AND NEUROLOGIX (PRODUCT LIABILITY)

138. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

139. Defendants Medtronic and Neurologix designed and manufactured the ABID System.

140. Defendants Medtronic and Neurologix are not providers of health care as defined in c. 231 sec. 60B.

141. By reason of the foregoing, defendants Medtronic and Neurologix , their agents, servants and/or employees have violated statutes, codes, laws, ordinances, rules and regulations and are liable to plaintiffs by reasons of such violations.

142. The ABID System was manufactured in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to said Act.

143. The ABID System was manufactured in violation of the terms, conditions, standards and specifications of the Investigational Device Exemption ("IDE") secured by Satiety from the Food and Drug Administration's Premarket Approval Process ("PMA").

144. Defendants Medtronic and Neurologix negligently manufactured and/or designed the ABID System by:

a. designing, manufacturing, and/or distributing a product in a defective condition;

b. designing, manufacturing, and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, and/or distributing a product for which it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, and/or distributing a product which was defective and which could cause injury to the user;

k. failing to exercise reasonable care in the design of this product;

l. failing to exercise reasonable care in the distribution of this product;

m. failing to adequately and properly test this product;

n. failing to use reasonable care under the circumstances;

o. delivering a product which was defective and could cause injury to the user;

p. producing a product which was defective and could cause injury to the user;

q. supplying a product which was defective and could cause injury to the user;

r. failing to adequately and properly test the product after its design and manufacture;

s. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

t. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

145. As a direct and proximate result of the negligence of Defendants Medtronic and Neurologix as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

146. Also, the negligence of Defendants Medtronic and Neurologix as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, Plaintiff Robert Zeman demands judgment against Defendants Medtronic, Inc. and Neurologix, Inc. in the sum of Fifteen Million ($15,000,000.00) Dollars, plus interest and costs.

## COUNT XIII
## BREACH OF WARRANTY AGAINST MEDTRONICS AND NEUROLOGIX (PRODUCT LIABILITY)

147. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

148. At all times relevant to the Complaint, Defendants Medtronic and Neurologix were in the business of designing, manufacturing, and/or selling, medical devices such as the ABID System.

149. At the time they manufactured, sold, and/or placed the ABID System into the stream of commerce as aforesaid, Defendants Medtronic and Neurologix impliedly

warranted that said ABID System was of merchantable quality and fit for the purpose for which it was intended.

150. At the time the aforementioned ABID System last left the possession, custody or control of Defendants Medtronic and Neurologix, said ABID System was defective in design and/or manufacture, was unreasonably dangerous, and was in breach of the aforementioned implied warranties.

151. As a direct and proximate result of the negligence of Defendants Medtronic and Neurologix as aforesaid, Plaintiff Zeman was caused to suffer serious and permanent injury and pain of body and anguish of mind, and has been and will continue to be unable to pursue his normal activities.

152. Also, the negligence of Defendants Medtronic and Neurologix as aforesaid was a direct and proximate cause of the reduction or elimination of Plaintiff Zeman's chance at achieving a more favorable medical outcome.

**WHEREFORE**, Plaintiff Robert Zeman demands judgment against Defendants Medtronic, Inc. and Neurologix, Inc. in the sum of Fifteen Million ($15,000,000.00) Dollars, plus interest and costs.

## COUNT XIV
## LOSS OF CONSORTIUM
## VS. ALL DEFENDANTS

153. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

154. As a result of the conduct of defendants as described above, Plaintiff Julia Zeman was deprived of the society, comfort, services, and consortium of her husband Plaintiff Zeman.

**WHEREFORE**, Plaintiff Julia Zeman demands judgment against:

A. Defendants Ziv Williams, M.D., Emad Eskandar, M.D., and the Individual IRB Members, for her damages based on their liability as set forth in counts I through X, in a sum to be adjudged by a jury, plus interest and costs; and

B. Defendants Medtronic, Inc. and Neurologix, Inc., for her damages based on their liability as set forth in counts XI through XIII, in the sum of Three Million ($3,000,000.00) Dollars, plus interest and costs.

**PLAINTIFFS DEMAND TRIAL BY JURY ON ALL COUNTS.**

Dated: April 20, 2011

The Plaintiffs,
By their attorneys,
/s/ Scott E. Charnas
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## CERTIFICATE OF SERVICE

I, Scott E. Charnas, hereby certify that on April 20, 2011, a copy of the within Plaintiffs' Amended Complaint was served upon the following counsel of record by electronic mail and by first class mail, postage prepaid:

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