WRIGHT COMPLAINT

KITSAP COUNTY SUPERIOR COURT IN AND FOR THE STATE OF WASHINGTON

WILLIAM LEE WRIGHT, Sr., individually and:

as Personal Representative of the Estate of Becky:

Wright; PEGGY DRAHEIM, individually and :

as Personal Representative of the Estate of :

Dr. John Draheim; and all others similarly :

situated, :

:

Plaintiff, :

: CAUSE NO.: 01-2-008376

vs. :

THE FRED HUTCHINSON CANCER : FIRST AMENDED

RESEARCH CENTER; DR. E. DONNALL : COMPLAINT FOR

THOMAS and JANE DOE THOMAS, and : DAMAGES AND

the marital community comprised thereof; : CLASS ACTION

DR. JOHN A. HANSEN and JANE DOE :

HANSEN, and the marital community comprised:

thereof; DR. PAUL J. MARTIN and JANE :

DOE MARTIN and the marital community :

comprised thereof; DR. ROBERT DAY and :

JANE DOE DAY, and the marital community :

comprised thereof; and GENETIC SYSTEMS :

CORPORATION and its PRESENTLY :

UNKNOWN SUCCESSOR CORPORATION, :

:

Defendants. :

:

I. INTRODUCTION

1. Plaintiffs bring this action pursuant to Rule 23 of the Washington Rules of Civil Procedure on their own behalf and as representatives of a class of persons consisting of: All persons who participated in Protocol 126 at the Fred Hutchinson Cancer Research Center between 1981 and 1993, (a "Study Participant") or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue the defendants herein independently or derivatively by reason of their personal relationship with a Study Participant, including without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("Derivative Claimants").

2. Plaintiffs bring this action individually and as class representative to recover damages, against the defendants identified below who created, took part in and formulated Protocol 126.

II. PARTIES AND VENUE

3. Plaintiff William Lee Wright, Sr., is a resident and citizen of the State of Alabama residing at 960 Ross St., Heflin, Alabama, 36364.

4. Plaintiff William Lee Wright, Sr. was the husband of plaintiff's decedent Becky Wright.

5. Plaintiff William Lee Wright, Sr. was duly appointed Administrator of the Estate of Becky Wright.

6. Plaintiff Peggy Draheim, is a resident and citizen of the State of Arizona residing in Scottsdale.

7. Plaintiff Peggy Draheim was the wife of plaintiff's decedent Dr. John Draheim.

8. Plaintiff Peggy Draheim was duly appointed Administrator of the Estate of Dr. John Draheim.

9. The plaintiff Class consists of :

All persons who participated in Protocol 126 at the Fred Hutchinson Cancer Research Center between 1981 and 1993 ("Research Subjects"), or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue the Defendants independently or derivatively by reason of their personal relationship with a Research Subject, including

without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("Derivative Claimants").

On information and belief, a substantial number of the putative members of the Class were residents of the State of Washington at the time they received services from the defendants and/or their estates were estates filed in Washington. On information and belief, one of the said putative members of the Class is the estate of Dr. John Draheim. Dr. Draheim was a resident of Bremerton, Kitsap County, Washington during the relevant time period. Venue is proper, therefore, in Kitsap County Superior Court.

10. Defendant The Fred Hutchinson Cancer Research Center ("the Center") is a medical facility organized and existing under the laws of the State of Washington with its principal office and place of business located at 110 Fairview Ave. N., Seattle, Washington, 98109.

11. Defendant Dr. E. Donnall Thomas is the co-founder and clinical director of the Center and and is a citizen of the United States and the State of Washington.

12. Defendant Dr. John A. Hansen at all times relevant hereto was the head of a tissue-typing lab and later clinical director at the Center and is a citizen of the United States and the State of Washington.

13. Defendant Dr. Paul J. Martin at all times relevant hereto was an oncologist employed by the Center and and is a citizen of the United States and the State of Washington.

14. Defendant Dr. Robert Day at all times relevant hereto was

the Director of the Center and is a citizen of the United States and the State of Washington.

15. Defendant Genetic Systems is a corporation incorporated on Nov. 13, 1980, whose successor entity is presently unknown but believed to be a corporation.

CLASS ACTION ALLEGATIONS

16. Plaintiffs bring this action, pursuant to Rule 23 of the Washington Rules of Civil Procedure, on their own behalf and as representatives of the following class of individuals:

All persons who participated in Protocol 126 at the Fred Hutchinson Cancer Research Center between 1981 and 1993 ("Research Subjects"), or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue the Defendants independently or derivatively by reason of their personal relationship with a Research Subject, including without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("Derivative Claimants").

17. Plaintiffs and the Class bring this action for damages pursuant to Rule 23 of the Washington Rules of Civil Procedure.

18. Research Subjects have suffered personal injury and death as a direct and proximate result of defendants' actions herein. In addition, the Derivative Claimants have suffered damages as a direct and proximate result of the defendants' actions for which an award of damages is appropriate.

19. The named plaintiffs herein are members of the Class they seek to represent.

20. The Class includes approximately 82 individuals, and therefore the members of the Class are so numerous that joinder is impracticable.

21. There are questions of law and fact common to the class including, but not limited to:

1. whether defendants failed to follow and abide by the Nuremberg Code, the Belmont Report, the Declaration of Helsinki and 45 CFR ' 46;

2. whether defendants knew of prior adverse reactions to the drugs used in Protocol 126 and failed to inform the Research Subjects of these adverse reactions;

3. whether the defendants failed to adequately and properly test the drug after its design and manufacture;

4. whether the defendants failed to investigate and analyze prior adverse reactions information in order to warn and/or notify Research Subjects of the dangers of participating in the program;

5. whether defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial;

6. whether defendants' misrepresentations set forth above were done with the knowledge that they were false when made;

7. whether, by their actions, defendants increased the risk of harm, thereby causing the injuries and/or death of the plaintiff and other members of the class;

8. whether defendants conducted adequate study, testing and analysis to determine whether Protocol 126 was harmful to Research Subjects;

9. whether defendants engaged in unconscionable, deceptive and/or unreasonable business practices and conduct;

10. whether defendants knowingly, or intentionally concealed, suppressed or omitted material information intended to be relied upon by others in connection with Protocol 126;

11. whether the class has been injured by virtue of defendants intentional, reckless, careless and/or unconscionable and/or deceptive business practices and conduct;

12. whether defendants falsely and fraudulently misrepresented in its advertisements, promotional materials and other materials the safety and adverse results of participating in Protocol 126;

13. whether defendants knew or should have known that participating in Protocol 126 posed a substantial increased risk of serious adverse health effects including but not limited to death;

14. whether defendants continued to recruit individuals to participate in Protocol 126 notwithstanding their knowledge of the dangerous nature of the Protocol;

15. whether defendants earned substantial profits as a result of their conduct herein;

16. whether defendants knowingly omitted, suppressed or concealed material facts about the unsafe and dangerous

nature of Protocol 126 from government regulators, the Institutional Review Board, the medical community and/or the consuming public;

17. whether defendants wrongful conduct as described above violated the provisions of the Washington Health Care Provider Act, RCW 7.70.030, subpart (1),(2) and (3); and,

18. whether defendants wrongful advertising, marketing and/or other business conduct constitute false, deceptive and/or unfair business practices in violation of the Washington Consumer Protection Act, RCW 19.86 et seq.

22. These and other questions of law and/or fact are common to the class and predominate over any questions affecting only individual class members.

23. The claims of the named plaintiffs are typical of the claims of the class they seek to represent, in that the named plaintiffs and all members of the proposed class participated in Protocol 126 and assert rights and claims as a "Derivative Claimant" or "Representative Claimant" as these terms are defined in the proposed class definitions.

24. The proposed class seeks damages as a result of injuries they or their heirs have sustained as a result of defendants' conduct. In addition, the Derivative Claimants have suffered a loss of consortium, love, services, and affection, and have incurred financial expenses and economic losses as a direct and proximate result of the personal injuries and damages suffered by their spouses or significant others who were Research Participants. Thus, the pursuit of damages by the class representative for their injuries and losses will work to benefit the entire proposed class they seek to represent.

25. Plaintiffs will fairly and adequately represent and protect the interests of the members of the class they represent. The named plaintiffs have retained counsel competent and experienced in complex class actions and litigation involving clinical research to represent them and the members of the class. Accordingly, the interests of the class will be adequately protected and advanced. In addition, there is no conflict of interest between the named plaintiffs and the members of the class. The interests of the named plaintiffs are aligned because the members of the class have an interest in securing their right to compensatory damages as a consequence of any injuries caused by defendants' conduct.

26. Notice can be provided to class members by a combination of published notice and first class mail since defendants are in possession of the addresses of those individuals who participated in the Protocol 126.

27. Certification of the class is appropriate because the questions of law and fact common to the members of the class predominate over any questions affecting only individual members. This class action is superior to other available remedies for the fair and efficient adjudication of this controversy.

FACTUAL BACKGROUND

The Protocol

28. In November of 1980, defendant Genetic Systems Corporation was formed by Mr. David Blech.

29. The purpose of Genetic Systems was to recruit physicians who treat cancer patients in exchange for a position on the

board of Genetic Systems and stock in the company.

30. In December of 1980, defendants Hansen, Thomas and Martin submitted Protocol 126 to the Human Subjects Review Committee ("HSRC") of the Fred Hutchinson Cancer Research Center (the "Center").

31. The purported goal of Protocol 126 was to prevent an immune-system reaction known as graft-versus-host disease ("GVHD") which occurs in approximately 50% of recipients of bone marrow transplants from tissue-matched siblings.

32. In approximately 95% of the patients, GVHD is not fatal.

33. In January of 1981, one month after submitting Protocol 126 to the HSRC, defendant Genetic Systems gave to defendant Hansen 250,000 shares of its stock and an $18,000 consulting fee.

34. In January of 1981, Genetic Systems gave to defendant Thomas, 100,000 shares and a $3,000 a year board position.

35. In January of 1981, Genetic Systems gave to defendant Martin 10,000 shares of Genetic Systems stock.

36. In January of 1981, the HSRC rejected Protocol 126 stating that it may cause graft rejections and cancer relapses.

37. In March of 1981, Genetic Systems signed a 20 year deal with the Center for commercial rights to 37 substances, including three to be tested in Protocol 126. In exchange for this agreement, the Center received money and a royalty agreement while an affiliated foundation received stock in Genetic Systems.

38. In April of 1981, defendant Hansen resubmitted Protocol 126 which was approved by the HSRC.

39. At no time was the HSRC told that defendants Hansen, Thomas, Martin or the Center had a financial interest in Genetic Systems.

40. At no time was the HSRC told that defendants Hansen, Thomas, Martin or the Center had a direct financial interest in the outcome of Protocol 126.

41. The informed consent form that the participants signed minimized the risk of graft failure and made it sound as if a second bone marrow transplant could be done without difficulty if the first one failed.

42. The defendants knew that the salvage rate from second bone marrow transplants was between 5 percent and 10 percent.

43. In December of 1981, defendant Martin sought and obtained approval of a revised Protocol 126 by adding agents that greatly increased the killing power of the monoclonal antibodies used in the experiment.

44. In March of 1983, the Center adopted a new conflict of interest policy whereby scientists were prohibited from participating in any research involving the Center in which the member had a financial interest.

45. Despite this revised policy, defendants Hansen, Thomas and Martin continued to participate in Protocol 126.

46. In April of 1983, the interests of the individual defendants in Genetic Systems was as follows: Thomas - $916,000; Hansen - $2,000,000; Martin - $91,000; and the Foundation - $458,000.

47. In April of 1983, the HSRC sought certain stopping criteria if individuals died in the trial as well as a change in the consent form warning of unexpected new cancers.

48. Despite this new stopping criteria and despite the fact that numerous patients had died while participating in Protocol 126, defendants never reported the deaths to the HSRC.

49. In the spring of 1983, the trial was again approved but the consent form failed to disclose the risks of new cancers, relapse and graft failure.

50. During this month, defendant Hansen was named vice president for research of Genetic Systems.

51. In September of 1983, the HSRC was renamed the Institutional Review Board ("IRB").

52. In September of 1983, the IRB asked for clarification on the animal tests, human risks and financial interests involved in Protocol 126.

53. In response to this request, defendant Thomas denied any conflict of interest, refused the IRB's request for separate tests on antibodies and warned the IRB not to impede research.

54. In January of 1984, defendant Hansen began a one year leave from the Center to be medical director for Genetic Systems.

55. Over the next several years, despite concerns over the financial interests of the researchers and Protocol 126 in general, the Center allowed Protocol 126 to continue.

56. In March of 1984, defendant Martin failed to notify IRB or medical examiner of treatment-caused deaths as required by law.

57. In May of 1984, Nancy Haldeman left the IRB administrator stating the Center did not want independent oversight.

58. Additionally, the IRB approved the next phase of trial but suggested that it should go through outside review.

59. Thereafter, defendant Day refused outside review of Protocol 126.

60. In January of 1985, the IRB approved Protocol 126.2 for three months, excluding good-prognosis patients. The consent form still failed to mention the known risks of participating in Protocol 126.

61. In April of 1985, defendants Martin, Hansen and Thomas applied for Protocol 126.3, combining T-cell depletion with other chemicals. The IRB again asked for outside review.

62. In October of 1985, Genetic Systems was bought out by Bristol-Myers for $294 million, or $10.50 per share, making the original interest of Defendant Thomas worth $1.05 million, the foundation $502,000, and defendant Martin $105,000. Defendant, Hansen, who had sold some shares, held stock worth $1.8 million.

63. Prior to September of 1985, defendant Martin told his colleagues that Protocol 126 had prevented GVHD but caused between 35 percent and 40 percent graft failures vs. an expected 1 percent.

64. In April of 1988, defendant Martin presented a paper

saying T-cell depletion in certain leukemia patients led to 100 percent relapse rate vs. expected 25 percent.

65. In 1991, ten years after the start of Protocol 126, defendant Martin proposed Protocol 126.7.

66. The consent form for Protocol 126.7 finally stated: "There is a chance that the donor marrow will fail to produce new blood cells because of rejection or other problems. In this situation, there is a high chance of infections, bleeding and death."

67. Presently, the value of defendant Thomas' original stock is about $5 million, the foundation's $2.5 million, defendant Martin's $525,000 and defendant Hansen's shares are worth $9 million.

68. Eighty of eighty-two patients are dead from graft failures and/or leukemic relapse attributable to the treatment.

69. In 1984, Dr. John Draheim, then a resident of Bremerton, Washington came to the Fred Hutchinson Center for chemotherapy, radiation and bone marrow transplants. His bone marrow transplant failed to engraft and as a result he died. Based upon information and belief, Dr. Draheim was subjected to treatment by Fred Hutchinson Center under Protocol 126 without adequate informed consent of the risks of the Protocol and other available Protocols as required by Washington law. Fred Hutchinson Center concealed from Dr. Draheim material facts relating to the treatment and the Protocol.

70. In 1985, plaintiff's decedent Becky Wright went to the Fred Hutchinson Cancer Research Center to undergo a bone

marrow transplant.

71. Within weeks after receiving this transplant, Becky Wright was dead, a direct result of the treatment she received from the defendants.

72. At no time prior to her participation in Protocol 126 was Becky Wright informed of the true nature of risks she was encountering by taking part in Protocol 126.

73. At no time prior to her participation in Protocol 126 was Becky Wright informed that the individual defendants had a direct financial interest in the Protocol.

74. At no time prior to her participation in Protocol 126 was Becky Wright informed that the salvage rate of second transplants was approximately five-ten percent.

75. At no time prior to her participation in Protocol 126 was Becky Wright informed that two of the first nine patients using one of the antibodies in Protocol 126 suffered new cancers and died.

76. At no time prior to her participation in Protocol 126 was Becky Wright informed that the procedure increased the chances of a relapse because GVHD has an antileukemic effect.

77. At no time prior to her participation in Protocol 126 was Becky Wright informed that while GVHD was treatable, if it happened, leukemia relapses were usually fatal.

78. At no time prior to her participation in Protocol 126 was Becky Wright informed that there were alternative methods for treating GVHD if it occurred.

FIRST CAUSE OF ACTION

BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

79. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of themselves and all others similarly situated.

80. The Nuremberg Code and the Declaration of Helsinki are the minimum United States and international standards of conduct governing biomedical research on human subjects; they are in essence world statutes to which the citizens of all nations are subject.

81. The Nuremberg Code, drafted in response to the horrors of Nazi experimentation on human subjects, set forth basic principals Ato satisfy moral ethical and legal concepts.

82. The Nuremberg Code provides in pertinent part:

The voluntary consent of the human subject is absolutely essential. . . . . before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

. . .

The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history

of the disease or other problem understudy that the anticipated results will justify the performance of the experiment.

. . .

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

. . .

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

. . .

The experiment should be conducted only by scientifically qualified persons.

83. The World Health Organization established the Declaration of Helsinki to further the goals of the Nuremberg Code and to set the minimum acceptable standards in all nations in which human clinical trials are conducted. These include:

Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

. . .

The design and performance of each experimental procedure

involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

. . .

Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person..

. . .

Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject.

. . .

Concern for the interests of the subject must always prevail over the interest of science and society.

. . .

The right of the research subject to safeguard his or her integrity must always be respected.

. . .

Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazzards involved are believed to be predictable.

. . .

In any research on human beings, each potential subject must

be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

84. The common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial; such a right is a right of all citizens of the United States under the Constitutions of the United States and the State of Washington.

85. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiffs and the members of the class to be treated with dignity.

86. As a result of defendants' actions, plaintiffs and the members of the class have suffered damages.

SECOND CAUSE OF ACTION

21 CFR '210, 211/21 CFR '601, 610/45 CFR '46

87. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of themselves and all others similarly situated.

88. 21 CFR '210, 211 and 21 CFR '601, 610, part of the code of Federal Regulations, establish the law of the United States with respect to the manufacture and control of investigational biological drugs for clinical use.

89. 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 the Center.

90. These latter 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.

91. These regulations also require institutions such as the Center to appoint an IRB to oversee the Trial and to adhere to the opinions and directives of the IRB.

92. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiffs and the members of the class.

THIRD CAUSE OF ACTION

THE BELMONT REPORT

Breach of the Assurance Agreement

93. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and all others similarly situated.

94. The Center agreed that all human research at the Center would be conducted in accordance with the Belmont Report.

95. This agreement is contained in a document known as the AMultiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects" ("Assurance Agreement").

96. This Assurance Agreement in essence is a contract between the Center and the Department of Health and Human Services; plaintiffs' decedents and the other members of the class were third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at the Center.

97. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR'46.

98. As a result of this breach, plaintiff and other members of the class have suffered damages as set forth above.

FOURTH CAUSE OF ACTION

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

99. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of themselves and all others similarly situated.

100. Defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial.

101. The misrepresentations set forth above were done with the

knowledge that they were false when made.

102. Plaintiffs' decedents and the members of the class justifiably relied upon the above stated misrepresentations in making the decisions to participate and continue in the Trial.

103. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiffs' decedents and other members of the class participated and continued in the Trial to their detriment.

FIFTH CAUSE OF ACTION

ASSAULT, BATTERY, AND VIOLATION OF

HEALTH CARE PROVIDER ACT

104. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and alleges as follows on behalf of themselves and all others similarly situated.

105. Defendants failed to inform the plaintiffs' decedents and other members of the class of the risks of all treatment, care, therapy and procedures performed so as to afford the plaintiffs and the members of the class the opportunity to make an informed decision as to the performance of said procedures in violation of the Washington Health Care Provider Act, RCW 7.70.030(3); thus the therapy plaintiffs and other members of the class received constituted a battery.

106. Defendants through their negligent and wrongful conduct, as described herein, and through their assurances and promises of treatment under Protocol 126 violated the Washington Health Care Provider Act, RCW 7.70.030(1) and (2).

SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of themselves and all others similarly situated.

107. Defendants designed, manufactured and supplied the biologics which caused great physical and emotional damage to the plaintiffs' decedents and the members of the class.

108. Defendants breached their duties and obligations to the plaintiffs' decedents and the members of the class by various sections of the Revised Code of Washington, Section 7.72 and Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to the plaintiff by:

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

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

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

4. failing to have adequate warnings on the product;

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

6. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured

more safely;

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

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

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

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

11. failing to ensure that ultimate users were advised of the dangers of said product;

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

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

14. failing to adequately and properly test this product;

15. failing to use reasonable care under the circumstances;

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

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

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

19. knowing of prior adverse reaction to the drugs and failing to inform the user of these adverse reactions;

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

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

22. violating applicable sections of the Restatement of Torts, 2d; and

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

109. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the death of the plaintiffs' decedents and the injuries and/or death of other members of the class.

SEVENTH CAUSE OF ACTION

VIOLATION OF CONSUMER PROTECTION ACT

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

111. Defendants' wrongful conduct in advertising and marketing Protocol 126, and in failing to disclosed their financial and business interests in the sale and marketing of

the Protocol to patients, including plaintiffs and the members of the plaintiff class, engaged in false, deceptive and/or unfair conduct in violation of the Washington Consumer Protection Act, RCW 19.86 et seq.

112. Defendants' wrongful conduct in violation of the Washington Consumer Protection Act caused economic injury to plaintiffs and the members of the plaintiffs' class.

DAMAGES

Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges on behalf of themselves and all others similarly situated.

113. As a direct and proximate result of defendants' acts, omissions and conduct as set forth above, plaintiffs and the members of the class have suffered personal injury, wrongful death, loss of consortium, emotional distress, out of pocket expenses, and/or economic loss. .

114. Plaintiffs, on their behalf, in their representative capacity, and on behalf of the members of the Class are entitled to exemplary and/or punitive damages up to the maximum amount permitted by applicable law based upon the wrongful, intentional, reckless and/or unfair, fraudulent or deceptive conduct of the defendants.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the plaintiff Class pray for relief as follows:

A. That this action be certified as a class action pursuant to Rule 23 of the Washington Rules of Civil Procedure;

B. That plaintiffs and the Class members be awarded their above claimed damages;

C. That plaintiffs and the Class members be awarded their actual and reasonable attorneys' fees, expenses and costs of this action, as provided by applicable law; and

D. That plaintiffs and the Class members be awarded any other relief in law or equity to which the plaintiffs and the members of the plaintiff Class are entitled.

DATED: March 29, 2001.

SHORT CRESSMAN & BURGESS, P.L.L.C.

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David E. Breskin, WSBA #10607 Attorneys For Plaintiffs and the Plaintiff Class

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_____

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