IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WASHINGTON, AT SEATTLE

ALLAN BERMAN., individually and as as Personal Representative of the Estate of Kathryn Hamilton, Plaintiff,	**:**	**CAUSE NO.** **CASE RELATED TO: C 01-5217 RSL**
vs. THE FRED HUTCHINSON CANCER RESEARCH CENTER; DR. WILLIAM BENSINGER; DR. C. DEAN BUCKNER; DR. FREDERICK APPLEBAUM; and DR. ROBERT DAY; Defendants.	**:**	**JURY DEMANDED**

I. INTRODUCTION

1. Plaintiff brings this action on his own behalf and as personal representative of the estate of Kathryn Hamilton.

II. VENUE

2. Allan Berman is a resident of Spokane County, Washington.

3. Defendant Fred Hutchinson Cancer Research Center transacts business in every county in Washington, including King.

4. Venue is proper in the Western District of Washington at Seattle.

III. PARTIES

5. Plaintiff, Allan Berman, is the husband and personal representative of Plaintiff=s decedent, Kathryn Hamilton.

6. Defendant The Fred Hutchinson Cancer Research Center (Athe 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.

7. Defendant Dr. William Bensinger was the supervisor of Protocol 681 at the Fred Hutchinson Cancer Research Center between 1991 and 1998 and is a citizen of the United States and the State of Washington.

8. Defendant Dr. C. Dean Buckner was an investigator on Protocol 681 at the Fred Hutchinson Cancer Research Center and is a citizen of the United States and the State of Washington.

9. Defendant Dr. Frederick Applebaum is the director of clinical research at the Fred Hutchinson Cancer Research Center and was one of the investigators on Protocol 681 and is a citizen of the United States and the State of Washington.

10. 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.

IV. FACTUAL BACKGROUND

The Protocol

11. Prior to 1990, with federal funding, Dr. James Bianco, while an employee or agent of Fred Hutchinson Cancer Research Center, had done a preliminary study of 30 patients and concluded that pentoxifylline (APTX@) used for treating leg cramps could shield the liver, kidney and soft linings of the digestive system from the toxic damage of chemotherapy.

12. The Fred Hutchinson Cancer Research Center and the individual defendants knew or should have known that:

12.1 Dr. Bianco was unable to replicate his initial findings regarding PTX.

12.2 A second PTX study by Bianco indicated PTX patients experienced increased chances of kidney damage.

12.3 In the first study, Dr. Bianco claimed only 3 percent of patients taking PTX suffered kidney damage following chemotherapy. In the second study, 39 percent suffered kidney damage.

12.4 That was greater than the percentage - 36 percent - who suffered kidney damage from chemotherapy and a placebo sugar pill. Dr. Bianco knew PTX patients had a significantly increased chance of experiencing severe kidney damage following chemotherapy.

12.5 By January 1992, one year before Plaintiff=s decedent was admitted to Protocol 681, defendants knew the PTX studies= results. Not only was PTX not a miracle drug, defendants had evidence indicating it might make patients sicker.

12.6 Dr. Bianco pulled the medical charts of patients who in addition to receiving PTX had been given other drugs known to alter the way drugs metabolize. He found 10 patients who, in course of being treated with PTX, had also been given the antibiotic Cipro and a steroid called prednisone.

12.7 Dr. Bianco concluded none of the 10 patients had suffered damage to her kidneys, livers or lungs. These findings were used to help justify the human experiment known as Protocol 681 that plaintiff Hamilton enrolled in during January 1993.

12.8 Dr. Bianco=s conclusions about Cipro and prednisone used with PTX were in error and all defendants knew or should have known this before Protocol 681 was instituted.

12.9 Dr. Bianco along with Dr. Jack Singer decided to start their own company to develop the treatment of breast cancer patients with PTX, Cipro and prednisone.

13. Dr. Bianco and Dr. Singer worked with New York investment banker David Blech (who had started Genetic Systems) and together they founded Combined Therapeutics Inc. in September 1991. The name soon changed to Cell

Therapeutics Inc., or CTI.

14. Dr. Bianco and Dr. Singer left The Hutch to work on their new company full time.

15. Dr. Bianco sought The Hutch=s collaboration in researching the treatment.

16. The Hutch's president, Defendant Dr. Robert Day, wanted the cancer center to be compensated for the plan to commercialize Bianco=s research. A deal was made including the following terms: The Hutch would receive about $20,000 in stock shares and $50,000 a year in licensing fees. That would increase to at least $100,000 plus a percentage of sales if the company successfully sold its treatment.

17. The Hutch stood to make millions if the drugs worked.

18. Dr. Bianco also recruited two prominent doctors, both Hutch co-founders, for CTI's scientific advisory board: Dr. E. Donnall Thomas and Dr. C. Dean Buckner, who would later become Plaintiff=s decedent=s doctor. Both received stock

options.

19. About this time another researcher, Dr. William Bensinger, was experimenting at The Hutch regarding stem-cell transplants in patients with advanced breast cancer.

20. He hadn't gotten far before a high dose of anti-cancer drugs killed two of four patients. Defendant Bensinger knew about Bianco's research and he sought the investigation of Bianco=s drug combination in Hutch patients being administered high-dosage chemotherapy.

21. Defendant C. Dean Buckner, who would soon join the Cell Therapeutics board, was working with Bensinger on Protocol 681. He and Bensinger knew PTX alone didn't work, but they hoped combining it with other drugs would make a difference.

22. The Protocol 681 proposal Bensinger submitted to The Hutch's Institutional Review Board (IRB) made no mention of generally known negative findings on PTX.

23. Dr. Bianco was of the opinion that there was no proof that PTX with other drugs worked, and until that was known, Bensinger wouldn't be able to tell whether his patients were tolerating higher doses of chemotherapy because of the drugs or despite them.

24. Dr. Bianco himself quickly gave up on PTX in combination with other drugs.

25. The reasons for Dr. Bianco giving upon on PTX in combination with other drugs are believed to include:

25.1 The FDA resisted the idea of combining two drugs into one. Bianco was trying to use one drug to change the way another drug broke down inside the body. The drugs might interact differently in different patients, so the plan to combine the drugs wasn't reliable;

25.2 Using an antibiotic such as Cipro was risky. Patients might develop a resistance to antibiotics,

making it more difficult to treat infections;

25.3 Because of business difficulties associated with using drugs manufactured by two different and competing companies, Bianco and CTI decided that it would not simply use both PTX and Cipro and, instead, would patent a compound that these two drugs created when mixed. This combination drug is known as Lisofylline.

26. The Hutch and the individual defendants knew or should have known what CTI was doing regarding PTX from CTI=s quarterly and annual reports. Anyone on the Cell Therapeutics advisory board, such as defendants Thomas or Buckner, would have known that Dr. Bianco was no longer backing PTX.

27. On November 15, 1992, the medical journal Blood published a study by Austrian and German doctors who had tried to replicate Bianco's first PTX study on 31 patients. They concluded that the drug didn't work.

28. Dr. Bianco publicly defended the challenge to the efficacy of PTX even though his own follow up study showed PTX was unsafe.

29. In the Fall, 1992, CTI was wrapping up its first major stock sale, raising $38.5 million.

30. In June 1993, CTI reported research results that suggest that PTX and Cipro were Awonder drugs.@

31. CTI claimed that 74 percent of the most seriously ill patients taking these drugs lived one year after treatment, compared with 7 percent of those who didn't take the drugs. It also claimed that after two years, 75 percent of the surviving patients were cancer-free, compared with 38 percent for those who didn't take the drugs.

32. No peer-reviewed proof was ever published in medical journals regarding CTI=s claims.

33. As CTI was touting its PTX research, it was shutting down that research. That led to The Hutch losing its supply of

the intravenous, liquid form of PTX.

34. The intravenous (or IV) form of PTX was not approved for use in the United States. While at The Hutch, however, Dr. Bianco had obtained permission from the FDA to use the IV form in clinical research. Dr. Bianco held onto that permission after leaving The Hutch, agreeing to supply the IV form to Hutch researchers for their continuing studies.

35. On November 10, 1992, CTI notified The Hutch that it was cutting off the IV supply of PTX.

36. Dr. Bianco no longer had a use for the IV form. All the defendants had to do, was ask the FDA for permission to use it.

37. Instead, Dr. Bensinger decided to stop using the IV form of PTX in Protocol 681. He sent a revised protocol to the Hutch's Institutional Review Board (AIRB@), which met monthly.

38. On January 5, 1993, the IRB ordered mention of the IV drug to be deleted from the informed-consent papers given to

patients entering the PTX study.

39. The next day, Plaintiff=s Decedent and her family met with Hutch doctor, Defendant Frederick Applebaum to decide whether she should enter Protocol 681.

40. Plaintiff=s Decedent read through the protocol and was prepared to ask questions when the family met with a Hutch doctor for the informed-consent conference.

41. Defendant Appelbaum, was one of the investigators on Protocol 681. He was also a co-author of two articles about PTX: one that showed promise and another, which was about to be submitted for publication, showing the drug didn't work.

42. Defendant Appelbaum never mentioned the new findings, even though the informed-consent form incorrectly said, "Recent studies suggest that PTX (pentoxifylline) prevents kidney, lung and liver damage in patients receiving transplants."

43. Defendant Appelbaum told Plaintiff=s Decedent that she would be given a large dose of anti-cancer chemicals: 18

milligrams of busulfan per kilogram of her body weight.

44. Then Dr. Applebaum explained to Plaintiff=s Decedent that the inevitable consequences of the (chemotherapytherapy) were nausea and vomiting.

45. That concerned Plaintiff=s Decedent. She had vomited violently during past treatments of radiation and chemotherapy.

46. The informed-consent form stated: PTX and Cipro "may be given through your Hickman catheter if your physician thinks you may not be absorbing the medicine when you take it."

47. The informed-consent form Plaintiff=s Decedent signed mentioned the availability of the IV version of PTX and/or Cipro more than once. But in fact, all defendants knew, or should have known, The Hutch no longer had the IV version of PTX. The Hutch had, but did not administer IV Cipro to Plaintiff=s Decedent.

48. Plaintiff=s Decedent signed the papers that day and was admitted immediately. At 6 p.m. January 6, 1993, she orally took her first PTX and Cipro pills. That night, she became nauseated and threw up. At 7 a.m. the next day, she was given her first dose of chemotherapy.

49. Plaintiff=s Decedent would finish taking the high doses of chemotherapy within her first week in the hospital.

50. She was supposed to take PTX for 31 days, but that didn't happen. Plaintiff=s Decedent struggled with nausea and vomiting from the first day, and nurses began noting that she was throwing up the PTX every time she took it.

51. The Hutch didn't ask the FDA for permission to use the IV form because it would have involved a lot of paperwork. However, Dr. Bianco had first obtained the liquid drug on an emergency basis simply by making a telephone call to the FDA. The Hutch could have done the same.

52. On January 15, 1993, Plaintiff=s Decedent underwent a stem-cell transplant.

53. Within days, she developed a fever, a sign of infection.

54. Plaintiff=s Decedent=s skin became yellow, and doctors found signs of liver damage. She had problems breathing. The blood vessels in her eyes, ears and nose began leaking, causing her to bleed.

55. On the evening of February 18th, her kidneys were failing.

56. The next morning, Plaintiff, Alan Berman talked to his wife for the last time. She pleaded with him not to let her die.

57. Six days after Plaintiff=s Decedent=s death, a group of 17 Hutchinson Center researchers submitted an article to the journal Blood - an article they had been working on for months. It said PTX was not effective in protecting against the toxic effects of chemotherapytherapy. Among the authors listed on the study were Bensinger, Appelbaum, Bianco and Singer.

58. Defendants continued Protocol 681.

59. Protocol 681 was designed to find the maximum amount of chemotherapy which patients could tolerate. A dose would be tested on four women and then escalated if none of these women died or suffered life-threatening complications from the chemotherapy. If two women died or suffered serious complications, the protocol stated, researchers must drop to a lower dose.

60. But the protocol didn't state what to do if one patient died.

61. A dose is considered lethal if a patient dies from it. At that point, doctors should stop the trial or continue to test at a lower dose.

62. In 1998, Defendant Bensinger shut down the study, one week after Cell Therapeutics reported disappointing results for its drug derived from the rescue drugs used in Protocol 681.

63. Kathryn Hamilton died from Protocol 681.

V. FIRST CAUSE OF ACTION

BREACH OF THE RIGHT TO BE TREATED WITH

DIGNITY

64. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and in his representative capacity.

65. 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.

66. 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.@

67. 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.

68. 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.**

69. 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.

70. 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 Plaintiff to be treated with dignity.

71. As a result of defendants= actions, plaintiffs have suffered damages.

VI. SECOND CAUSE OF ACTION

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

72. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and in his representative capacity.

73. 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.

74. 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.

75. 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.**

76. 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.

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

VII. THIRD CAUSE OF ACTION

THE BELMONT REPORT

Breach of the Assurance Agreement

78. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and in his representative capacity.

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

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

81. This Assurance Agreement in essence is a contract between the Center and the Department of Health and Human Services; Plaintiff=s Decedent was a third party beneficiary to this agreement in that the purpose of the agreement was to

protect a participant in clinical trials conducted at the Center.

82. 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.

83. As a result of this breach, plaintiffs have suffered damages as set forth herein.

VIII. FOURTH CAUSE OF ACTION

VIOLATION OF 42 U.S.C. ' 1983; ' 1985

84. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and in his representative capacity.

85. The University of Washington, the University of Washington School of Medicine, Department of Medicine, Division of Oncology, were at all times material to this action subdivisions, entities and/or agents of the State of Washington. Defendants Bensinger, Buckner and Appelbaum were at all

times material to this action associate professors or professors of the University of Washington School of Medicine, and were agents of the State of Washington in the performance of their duties at the defendant Fred Hutchinson Cancer Research Center with regard to their complained of acts or omissions relating to the development and use of Protocol 681, their failure to obtain the informed consent of Kathryn Hamilton to participate in Protocol 681 and their misrepresentations to Hamilton concerning her participation in Protocol 681 alleged herein.

86. The "Consent to Participate" form used by the defendant Fred Hutchinson Cancer Research Center and the above individually named defendants in order to obtain, and in failing to obtain, from Kathryn Hamilton her purported informed consent to participate in Protocol 681 states that it is the form of "Fred Hutchinson Cancer Research Center University of Washington School of Medicine Department of Medicine, Division of Oncology." The "Consent to Participate" form also identifies defendants Bensinger, Appelbaum and

Buckner as either associate or full professors of medicine of the University of Washington.

87. The University of Washington, the University of Washington School of Medicine, Department of Medicine, Division of Oncology, in their capacity as subdivisions, entities and/or agents of the State of Washington and acting under the color and authority of state law jointly acted with the defendants in creating, using and/or authorizing the use of the consent form through which the defendants purportedly sought, but failed, to obtain the informed consent of Kathryn Hamilton to participate in Protocol 681.

88. The University of Washington, the University of Washington School of Medicine, Department of Medicine, Division of Oncology, in their capacity as subdivisions, entities and/or agents of the State of Washington and acting under the color and authority of state law was so far insinuated into a postion of interdependence with the named defendants in defendants failure to obtain the informed consent of Kathryn

Hamilton to participate in Protocol 681 and in defendants' misrepresentations to Hamilton complained of herein concerning Protocol 681 and her participation in Protocol 681, that these subdivisions, entities and agents of the State of Washington jointly participated with the defendants in the complained of failure to obtain Hamilton's informed consent to participate in Protocol 681 and in defendants' misrepresentations to Hamilton concerning Protocol 681complained of herein.

89. The defendants' acts and omissions complained of herein were the acts and omissions of agents of the State of Washington and their failure to obtain the informed consent of Kathryn Hamilton and misrepresentations to Hamilton concerning Protocol 681 as set forth herein deprived Hamilton of her due process rights secured by the Fourteenth Amendment and her rights secured by the treaty, code, regulations and laws of the United States cited in paragraphs nos. 64-83 above under the color and with the actual or apparent authority of the State of Washington in violation of

42 U.S.C.' 1983. In conspiring to so deprive Hamilton of these rights, the named defendants also violated 42 U.S.C.' 1985.

IX. FIFTH CAUSE OF ACTION

COMMON LAW FRAUD/INTENATIONAL MISREPRESENATION

90. 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.

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

92. Plaintiff=s Decedent justifiably relied upon the above stated misrepresentations in making the decisions to participate and continue in the Trial.

93. As a direct and proximate result of defendants= intentional and material misrepresentations as set forth above,

Plaintiff=s Decedent participated and continued in the Trial to her detriment.

X. SIXTH CAUSE OF ACTION
ASSAULT, BATTERY, AND VIOLATION OF HEALTH CARE PROVIDER ACT

94. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and alleges as follows on behalf of himself and in his representative capacity.

95. Defendants failed to inform the Plaintiff= Decedent of the risks of all treatment, care, therapy and procedures performed so as to afford the Plaintiff=s Decedent 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 Plaintiff=s Decedent received constituted a battery.

96. Defendants through their negligent and wrongful conduct, as described herein, and through their assurances and

promises of treatment under Protocol 681 violated the Washington Health Care Provider Act, RCW 7.70.030(1) and (2).

XI. SEVENTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows on behalf of himself and in his representative capacity.

97. Defendants designed, manufactured and supplied the biologics which caused great physical and emotional damage to the Plaintiff=s Decedent.

98. Defendants breached their duties and obligations to the Plaintiff=s Decedent under 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.

99. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the death of the Plaintiff=s Decedent and compensable injury to the plaintiff.

XII. EIGHT CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION ACT

100. Plaintiff incorporates by reference the above stated paragraphs as if fully set forth at length herein.

101. Defendants' wrongful conduct in advertising and marketing Protocol 681, and in failing to disclose their financial and business interests in the sale and marketing of the Protocol to patients, including plaintiff, engaged in false, deceptive and/or unfair conduct in violation of the Washington Consumer Protection Act, RCW 19.86 et seq.

102. Defendants' wrongful conduct in violation of the

Washington Consumer Protection Act caused economic injury to plaintiff and the Plaintiff=s Decedent.

XIII. DAMAGES

Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges on behalf of himself and in his representative capacity.

103. As a direct and proximate result of defendants= acts, omissions and conduct as set forth above, Plaintiff=s Decedent and plaintiff have suffered personal injury, wrongful death, loss of consortium, emotional distress, out of pocket expenses, and/or economic loss.

104. Plaintiff=s Decedent and plaintiff 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.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. That Plaintiffs be awarded such damages as allowed at law or equity; B. That Plaintiffs be awarded their actual and reasonable attorneys' fees, expenses and costs of this action, as provided by applicable law; and

C. That Plaintiffs be awarded any other relief in law or equity to which they are entitled.

DATED: May 18, 2001.

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

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