Orig. Sig. of Atty from NJ to come -pm

ORIGINAL

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF NEW YORK

JAYNE STEUBING, individually and as Personal Representative of the Estate of CARL STEUBING, and all others similarly situated, **Albany, NY 12203**	**COMPLAINT FOR DAMAGES AND CLASS ACTION**
Plaintiff,	**NO.:** 03-CV-0332 TJM RFT
vs.	
PAUL KORNAK **Clifton Park, New York**	
and	
JAMES HOLLAND, M.D. **Voorheesville, New York**	**JURY TRIAL DEMANDED**
Defendants.	

I. INTRODUCTION

1. Plaintiff Jayne Steubing brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on her own behalf and as Personal Representative of the Estate of her late husband, Carl Steubing, and as representative of a class of persons consisting of all persons who participated in human subject research drug trials conducted by defendants Paul Kornak and

James Holland, M.D., at the Stratton Veterans Affairs Medical Center Hospital ("Stratton") between 1999 - 2003, ("Subjects") or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other person asserting the right to sue the defendants independently or derivatively by reason of their personal relationships with Subjects, including without limitation, spouses, parents, children, dependents, other relatives or significant others ("Derivative Claimants").

2. Plaintiff brings this action individually, as Personal Representative and as Class Representative to recover damages against the defendants identified below who created, took part in and formulated the human subject experiments at Stratton.

3. These experiments at Stratton were conducted contrary to the protocols, standards and regulations governing such research.

4. Federal authorities were warned seven years ago that veterans with cancer at Stratton were unduly suffering and were at risk of dying prematurely because they were being given drugs in violation of medical protocols; some former staff members complained that these veterans were treated as guinea pigs, a circumstance that unfortunately has been all too common in the history of medical care offered to America's veterans.

5. Veterans Affairs medical centers have conducted and continue to conduct a vast amount of medical research involving veterans funded by the pharmaceutical industry; veterans are considered an ample available resource for the research industry because veterans as a group are considered patriotic, civically minded and trusting of authority.

6. Investigators at these medical centers are many times given financial incentives to recruit and enroll subjects, a conflict of interest that compromises the scientific integrity of the studies and increases the danger to human subjects.

II. PARTIES/JURISDICTION/VENUE

7. Jayne Steubing is a resident and citizen of the State and Northern District of New York, residing in Albany, New York.

8. Jayne Steubing was the wife of decedent Carl Steubing.

9. Jayne Steubing was or will be duly appointed Administrator of the Estate of Carl Steubing.

10. The plaintiff Class consists of all persons who participated in human subject experiments conducted by defendants at Stratton between 1999 and 2003, or their estates, administrators or other legal representatives, heirs or beneficiaries, and any other persons asserting the right to sue the defendants independently or derivatively by reason of their personal relationships with Subjects, including without limitation, spouses, parents, children, dependents, other relatives or significant others.

11. On information and belief, a substantial number of the putative members of the Class were residents of the State and Northern District of New York at the time they received services from the defendants and/or their estates were filed in New York.

12. Defendant Paul Kornak, at all times relevant hereto, was an employee of the VA at Stratton, was the clinical assistant in the drug experiments and is a citizen of the United States with a residence in the State and Northern District of New York.

13. Defendant Dr. James Holland, at all times relevant hereto, was an employee of the VA at Stratton, was the lead physician in charge of the drug experiments and is a citizen of the United States with a residence in the State and Northern District of New York.

14. This is a civil action brought pursuant to *Bivens v. Six Unknown Named Agents of the Federal Bureau of Narcotics*, 403 U.S. 388 (1971). The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 2201.

15. Venue is proper pursuant to 28 U.S.C. §1391 in the Northern District of New York because the aforementioned experiments took place in Albany County, New York and both defendants reside in the State and Northern District of New York..

CLASS ACTION ALLEGATIONS

16. Plaintiff brings this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on her own behalf and as representative of the plaintiff Class.

17. The Subjects in the drug experiments 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.

18. The named plaintiff is a member of the Class.

19. The Class includes approximately 100 individuals and, therefore, the members of the Class are so numerous that joinder is impracticable.

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

a. whether defendants violated the Subjects' rights to bodily integrity under the Fifth Amendment to the United States Constitution;

b. whether defendants violated the Subjects' rights to essential human dignity under the Fifth Amendment to the United States Constitution;

c. whether defendants knew that certain Subjects were not eligible to participate in the drug experiments and yet still recruited and enrolled the Subjects;

d. whether defendants' actions as set forth above were done with the knowledge that they were acting in violation of the subjects' Constitutional rights and 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;

e. whether the class has been injured by virtue of defendants' conduct;

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

g. whether defendants continued to recruit and enroll the Subjects notwithstanding their knowledge of the dangerous nature of their experiments;

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

i. whether the Subjects suffered dignitary harm as a result of these Constitutional violations; and

j. Whether the defendants' conduct in making false promises to ill and terminally ill patients in order to lure them into becoming human subjects in their experiments is conduct that "shocks the conscience."

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

22. The claims of the named plaintiff are typical of the claims of the Class in that the named plaintiff and all members of the proposed class participated in the human research drug trials conducted by defendants at Stratton.

23. 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 Subjects. Thus, the pursuit of damages by the Class Representative for injuries and losses will work to benefit the entire proposed Class.

24. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. The named plaintiff has retained counsel competent and experienced in class actions and in litigation involving human subject research. Accordingly, the interests of the Class will be adequately protected and advanced. The interests of the named plaintiff are aligned with the Class 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.

25. 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 human research drug trials.

26. 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 Decedent – Carl Steubing

27. Born in 1922, Carl Steubing ("Mr. Steubing") was a valiant and courageous veteran who fought as an American soldier in the Battle of the Bulge during World War II where he earned the Purple Heart and Bronze Star.

28. After World War II, Mr. Steubing graduated from the Eastman School of Music and became known as the "Maestro," as leader of the Choralaires, a choir he founded in 1953 and led for twenty-four years.

29. Mr. Steubing was a modern Renaissance man who brought and inspired passion in all that he undertook.

30. Mr. Steubing was a painter, musician, composer, award-winning photographer, gourmet cook, downhill skier, golfer, fisherman, and avid sports fan.

31. Mr. Steubing had a day named in his honor by the Governor of New York and the state Senate and Assembly for his lifetime of extraordinary contributions to the community and to humanity.

32. In 1985, Mr. Steubing was diagnosed with colon cancer for which he underwent successful treatment.

33. In January 2001, Mr. Steubing was diagnosed with gastro-esophageal cancer by his private physician.

34. Soon thereafter, Mr. Steubing learned of a Phase III trial for patients with his type of cancer that was taking place at Sloan Kettering and at Stratton in Albany, New York.

35. Because of a two to three month wait period at Sloan Kettering, Mr. Steubing met with defendant Kornak who recruited and enrolled him in one of the seven human subject experiments taking place under his supervision and direction at Stratton.

36. The particular human subject experiment was protocol study RP56976V-325 which was an open label, randomized multicenter phase II/III study of Docetaxel in combination with Cisplatin (CDDP) or Docetaxel in combination with 5-Fluorouracil (5-FU) and CDDP compared to the combination of CDDP and 5-FU for patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for Advanced Disease.

37. Prior to enrolling Mr. Steubing in this experiment, defendants measured his blood chemistry and hematology.

38. Defendants purposefully and intentionally altered the dates of the blood chemistry and hematology reports in order to meet the assessment time frame criteria.

39. Further, Mr. Steubing's blood chemistry record indicated that he had a creatinine clearance value of 49.5 ml/mn and the exclusion criteria for creatinine clearance value in the experiment was less than 60ml/mn.

40. The defendants also took a history of Mr. Steubing and learned of the prior incidence of colon cancer, a history which would have rendered Mr. Steubing ineligible for participation in the experiment.

41. Willfully ignoring that Mr. Steubing's history, blood chemistry and hematology exposed him to increased risk of harm and suffering if he were to participate in the experiment, and for that reason made him ineligible for such participation, defendants enrolled Mr. Steubing and began testing the dangerous drugs on him.

42. In February 2001, Mr. Steubing received his first drug treatment and experienced severe adverse reactions to them.

43. By the July 2001, Mr. Steubing had finished the drug regimen.

44. On March 15, 2002, Mr. Steubing died after an infusion of taxotere and xeloda, leaving a wife, seven children and three grandchildren.

45. After Mr. Steubing's death, the Chief of Staff of Stratton informed Mrs. Steubing that her husband's condition may have been compromised by defendants' wrongful conduct and that he may not have been qualified for the study.

The Investigators – Kornak and Holland

46. In 1990, Paul Kornak was denied a medical license by the state of New Jersey because he falsified many of the documents he filed with his application.

47. Kornak had provided transcripts from a Polish medical school which he had created himself and altered undergraduate transcripts from the Junior College of Albany and the College of Saint Rose. He added courses which he had not taken; he raised most of the grades he received; he changed the cumulative averages; he redated the transcripts to reflect a more recent date; and he personally stamped the word "official" on both transcripts.

48. In 1991, the state of Iowa revoked Kornak's license for providing false information on a license application.

49. In 1992, Kornak was convicted of mail fraud for forging credentials when he tried to obtain a license in Pennsylvania. He was sentenced to three years probation and fined $2500.00.

50. Kornak never even applied to practice medicine in New York.

51. Dr. James Holland has a medical license to practice medicine in New York.

52. Dr. Holland was the Chief of Oncology at Stratton.

53. In 1999, Stratton hired Kornak with the knowledge that Kornak's medical license had been revoked; Kornak was not scientifically qualified to conduct human subject research at Stratton.

54. The defendants conducted seven clinical trials at Stratton on veterans with prostate cancer, bladder cancer, gastric cancer and colorectal cancer.

The Human Research Drug Trials

Study RP56976V-327 For Metastatic Hormone Refractory Prostate Cancer

55. After investigating the conduct of the defendants with respect to this clinical trial, the FDA found the defendants did not adequately adhere to the signed FDA form 1572 "Statement of Investigator" which states that the Investigator will personally conduct or supervise the described investigation protocol study.

56. Five of twenty-three subjects enrolled into study RP56976V-327 had altered ECGs, history and physical, and/or MUGA-LVEF records, which allowed the subjects to qualify for the study.

57. Five of twenty-three subjects enrolled into study RPS6976V-327 had altered records assessment protocol requirements and scheduled timeframes.

58. Four of twenty-three subjects enrolled into study RP56976V-327 had testosterone levels, PSA results, hematology, and/or biochemistry results reported in the subjects' case report forms, which were different than the results found in the source record VA-CPRS.

59. Fifteen of twenty-three subjects enrolled did not have an ECG performed as required by the protocol at the end of the study.

60. Fourteen of twenty-three subjects enrolled in the study did not have a MUGA-LVEF performed as required by the protocol at the end of the study.

61. Eight of twenty-three subjects enrolled in the study did not have all the required assessments performed; one or more tumor assessments were missed at baseline, week 6, 12, 21, 30 or end of the study as stated in the protocol.

62. Ten of twenty-three subjects enrolled in the study did not have all the required assessments performed; one or more bone scan assessments were missed at baseline, week 12, 21, 30 or end of the study as stated in the protocol.

63. Dose calculations for six of fifteen subjects reviewed for the RP56976V-327 study appeared to be inaccurate. Incorrect heights, weights and or body surface areas were documented in subject record files which attributed to inaccurate doses administered to each subject.

Study Demo-341-AJ For Superficial Bladder Cancer

64. After investigating the conduct of the defendants with respect to this clinical trial, the FDA found the defendants did not adequately adhere to the signed FDA form 1572 "Statement of Investigator" which states that the Investigator will personally conduct or supervise the described investigation protocol study.

65. Two of four subjects enrolled into study DFMO-341-AJ had altered records to meet eligibility requirements into the study.

66. Three of four subjects enrolled into study DFMO-341-AJ should have been excluded because they had clinically significant hearing problems.

67. Drug Accountability Records for three of four subjects enrolled in the DFMO-341-A1 have conflicting data in that the amounts dispensed, the amounts documented as taken, and the amounts returned by the subjects do not reconcile accurately.

68. The Drug Accountability Log maintained by defendants for the DFMO-341-A1 study is incomplete in that all lot numbers of bottles dispensed to subjects are not documented.

Study RP56976V-325 For Metastatic Or Locally Recurrent Gastric Cancer Previously Untreated With Chemotherapy For Advanced Disease

69. After investigating the conduct of the defendants with respect to this clinical trial, the FDA found the defendants did not adequately adhere to the signed FDA form #1572 "Statement of Investigator" which states that the Investigator will personally conduct or supervise the described investigation protocol study.

70. Two of six subjects enrolled into study RP56976V-325 had data entries made in the subjects' case report forms which were different than the data found in the source record.

71. One subject was enrolled into study RP56976V-325 even though the subject had blood and/or chemistry values at screening which excluded the subject from entry into the study.

72. Three of six subjects enrolled into study RP56976V-325 had previous malignant cancers, which excluded the subjects from the study.

73. One of six subjects enrolled into study RP56976V-325 had altered dates of blood chemistry and hematology reports to meet the assessment time frame criteria.

Study AVF-2107g For Metastatic Colorectal Cancer

74. After investigating the conduct of the defendants with respect to this clinical trial, the FDA found the defendants did not adequately adhere to the signed FDA form 1572 "Statement of Investigator" which states that the Investigator will personally conduct or supervise the described investigation protocol study.

75. Two of two subjects enrolled in the AVF-2108g study did not have urine dipstick (proteinuria) screening performed as required by the study protocol.

76. Two of two subjects enrolled into study AVF-2107g had data entries made in the subjects' case report forms which were different than the data found in the source record.

77. One subject had no twenty-four hour urine collection conducted after finding a '1+' urine dipstick result at screening to determine eligibility as required by protocol AVF-2107g and was entered into the study without waiver.

78. One subject had no twenty-four hour urine collection conducted after finding a '1+' and '2+' urine dipstick result as required by protocol AVF-2107g.

79. An adverse event of proteinuria was not reported in the case report form for two subjects as required by protocol AVF-210-7g.

80. For one subject enrolled in study AVF-2107g, no case report form was completed for treatment on 6/04/02 through the last day of treatment on 10/10/02l and the CRF thus does

not document administration of the study drug given on 6/18/02, 7/2/02, 7/16/02, 7/30/02, 8/6/02, 8/27/02, 9/10/02, and 10/10/02.

Study AVF-2192g-A3 For Metastatic Colorectal Cancer

81. After investigating the conduct of the defendants with respect to this clinical trial, the FDA found the defendants did not adequately adhere to the signed FDA form1572 "Statement of Investigator" which states that the Investigator will personally conduct or supervise the described investigation protocol study.

82. Three of five subjects enrolled in study AVG-2192g were not eligible for the study based on inclusion/exclusion criteria.

83. One of five subjects enrolled into study AVF-2192g had a data entry made in the subject case report form which was different than the data found in the source record.

84. Two of five subjects enrolled into study AVF-2192g had a history of congestive heart failure without the subjects' congestive heart failure being graded to determine eligibility of the subjects for participation in the study.

85. One subject had no twenty-four hour urine collection conducted after finding '1+' at screening, '2+' at Cycle 2 day 14, and '1+' at Cycle 3 as required by protocol AVF-2192g.

86. Adverse events of proteinuria were not listed in the case report form for two subjects as required by protocol AVF-2192g.

87. Incomplete case report forms exist for three of five subjects enrolled in the study AVF-2192g in that there is no documentation showing the study drug was administered when in fact other supporting records such as doctor's orders or nurse's notes document the drug was infused.

88. A protocol violation occurred for one subject during study AVF-2192g in that two out of fourteen doses were incorrectly calculated based on the subject's weight and then administered. The change in the subject's weight was not less than 10% and therefore did not meet the protocol requirement for a dose change.

Study RP56976V-326

89. Two of fourteen subjects enrolled into treatment B of study RP56976V-326 did not qualify for entry based on exclusion criteria calculated creatinine clearance values.

90. Two of two subjects enrolled in study RP56976.USI.203 were enrolled even though they did not meet eligibility requirements.

Study N91-00-02-079 For Chronic Cancer Pain

91. No case report form has been completed for one subject. As such, inclusion/exclusion criteria, medical history, screening, pain assessments, and administration of the study medication have not been completed.

FIRST CAUSE OF ACTION

FIFTH AMENDMENT RIGHT TO BODILY INTEGRITY

92. Plaintiff hereby incorporates all of the above paragraphs as if each were set forth in full herein.

93. At all relevant times, defendants were acting under color of federal law.

94. As specifically outlined in the facts above, Mr. Steubing and the class were the unwitting subjects of unethical human research conducted by defendants.

95. Defendants gave dangerous drugs and poked and prodded these subjects as part of the experiments which were conducted contrary to the respective protocols and contrary to the regulations and ethical norms governing such human subject research.

96. Defendants' conduct thus constituted a breach of the right to bodily integrity as guaranteed by the Fifth Amendment to the United States Constitution.

97. These actions of the defendants have caused Mr. Steubing and the class to suffer physical pain and suffering up to and including death as well as irreparable harm to their essential human dignity. Such actions have also caused the respective family members to suffer severe emotional distress, and the loss of consortium, companionship and support.

98. As a result, Mr. Steubing and each of the class members have suffered damages in a sum in excess of $1,000,000.00, and are also entitled to an award of punitive damages for the willful and malicious acts of defendants.

SECOND CAUSE OF ACTION

FIFTH AMENDMENT RIGHT TO ESENTIAL HUMAN DIGNITY

99. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

100. The Nuremberg Code is the minimum United States and international standard of conduct governing biomedical research on human subjects.

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

102. 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 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.

103. The standards of the Nuremberg Code reflect the right of every human subject to be treated with dignity in the conduct of human subject research.

104. The Fifth Amendment guarantees the right of every citizen to liberty and this liberty interest includes the right to essential human dignity in the context of human subject research.

105. Defendants' actions, as set forth above, fell below the minimum standards of conduct governing human subject research and were a breach of the right of Mr. Steubing and the class to this essential human dignity.

106. These actions of the defendants have caused Mr. Steubing and the class to suffer physical pain and suffering up to and including death as well as irreparable harm to their essential human dignity. Such actions have also caused the respective family members to suffer severe emotional distress, and the loss of consortium, companionship and support.

107. As a result, Mr. Steubing and each of the class members have suffered damages in a sum in excess of $1,000,000.00, and are also entitled to an award of punitive damages for the willful and malicious acts of defendants.

WHEREFORE, plaintiff Jayne Steubing, individually and as personal representative of the estate of Carl Steubing, and each of the class members, demand judgment against defendants, individually, jointly and severally, in an amount in excess of one million dollars ($1,000,000), together with punitive damages, interest, attorney's fees and costs of suit.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

ALAN C. MILSTEIN
DEREK T. BRASLOW
4300 Haddonfield Road, Suite 311
Pennsauken, NJ 08109
(856) 662-0700
(856) 665-0322-fax
NY0026

GREEN & SEIFTER

DONALD T. KINSELLA
90 State St. Suite 1440
Albany, N.Y. 12207
(518) 694-4600
NDNY Bar No.: 103149
Attorneys for Plaintiff and the Class

DATE: **March 18, 2003**