NORTH CAROLINA	**IN THE GENERAL COURT OF JUSTICE** **SUPERIOR COURT DIVISION**
ORANGE COUNTY	**03 CVS 1161**

WILLIAM C. HAMLET, **Plaintiff,** **v.** **GENENTECH, INC.;** **XOMA, LTD.;** **WESTERN INSTITUTIONAL REVIEW BOARD, INC.;** **PAREXEL INTERNATIONAL, LLC;** **MARK S. FRADIN, M.D.; and** **CHAPEL HILL DERMATOLOGY, P.A.,** **Defendants.**	)	**COMPLAINT AND DEMAND FOR JURY TRIAL**

The plaintiff complaining of defendants, alleges and says:

JURISDICTIONAL ALLEGATIONS

1. Plaintiff William C. Hamlet ("Mr. Hamlet") is a citizen of the state of North Carolina residing with his wife, Jennifer K. Nygard ("Ms. Nygard") in Pittsboro, North Carolina. Mr. Hamlet suffers no legal disability.

2. Defendant Genentech, Inc. ("Genentech") is a professional corporation, incorporated in the state of Delaware, that researches, discovers, develops, manufactures and markets biotherapeutics and biopharmaceuticals. Genentech has been involved, with defendant XOMA, Ltd., in the development of the investigational drug anti-CD11a (a.k.a., Raptiva, and hereinafter referred to as "the experimental drug"), which is an antibody being researched and developed for the treatment of psoriasis. Its registered agent is Corporation Service Company, 327 Hillsborough

Street, Raleigh, NC 27603.

3. Defendant XOMA, Ltd. ("XOMA") is a business entity formed under the laws of Bermuda. XOMA researches, develops and manufactures antibody and other protein-based biopharmaceuticals for disease targets that include immunological and inflammatory disorders. XOMA collaborated or worked in conjunction with Genentech in the research and development of the experimental drug. Its registered agent is Christopher J. Margolin, 2910 Seventh Street, Berkeley, California 94710.

4. Defendant Western Institutional Review Board, Inc. ("WIRB") is incorporated in the state of Washington. WIRB is an independent institutional review board the purpose of which is to, when contracted by a company with plans to conduct experimental drug studies or trials involving human subjects, protect the interests of patients either participating in, or considering whether to participate in, experimental drug studies or trials, and to monitor the clinical study or trial protocols to ensure the study or trial complies with federal regulations. Its registered agent is Angela Bowen, 3535 7th Avenue SW, Olympia, Washington 98502.

5. Defendant Parexel International, LLC ("Parexel") is a company organized under the laws of the state of Delaware. Parexel is a professional contract research organization in the business of conducting pharmaceutical clinical drug trials or studies. Its registered agent is CT Corporation, 225 Hillsborough Street, Raleigh, North Carolina 27603.

6. At all times relevant to this Complaint, each of these aforementioned defendants was involved in the business of pursuing the development and testing

of new pharmaceutical agents. In conducting its business, each of these defendants was engaged in substantial business activity within the State of North Carolina and, in particular, in Orange County.

7. Defendant Mark S. Fradin, M.D. ("Dr. Fradin") is a licensed dermatologist in medical practice at Chapel Hill Dermatology, P.A. located in Chapel Hill, North Carolina. Upon information and belief, Dr. Fradin is a resident of Orange County, and he suffers no legal disability.

8. Defendant Chapel Hill Dermatology, P.A. is a professional corporation organized under the laws of North Carolina which at all times hereinafter mentioned was doing business in Chapel Hill, North Carolina. Its registered agent is Stanley B. Levy, M.D., 891 Willow Drive, Suite 2, Chapel Hill, North Carolina 27514.

9. Dr. Fradin expressly and implicitly represented to the general public that he practiced medicine in a skilled and proper manner and possessed the degree of professional learning, skill and ability ordinarily possessed by other physicians who are engaged in the practice of dermatology in the same or similar communities.

10. Dr. Fradin was an employee and agent of defendant Chapel Hill Dermatology. All acts performed by Dr. Fradin which are contained in these allegations were performed during his employment with Chapel Hill Dermatology and were performed within the course and scope of his employment.

11. In compliance with Rule 9(j) of the Rules of Civil Procedure, the medical care provided by Dr. Fradin has been reviewed by a person who is reasonably expected to qualify as an expert witness under Rule 702 of the Rules of Evidence and

who is willing to testify that the medical care provided by this defendant did not comply with the applicable standard of care.

12. Jurisdiction lies in the Superior Court Division because plaintiffs seek to recover in excess of $10,000 for compensatory damages.

FACTUAL ALLEGATIONS

13. Mr. Hamlet was a patient at Chapel Hill Drematology since 1984, where he was treated for psoriasis. Since 1991, Mr. Hamlet was a patient of Dr. Fradin. In 1992, Mr. Hamlet was diagnosed with psoriatic arthritis. Mr. Hamlet's psoriatic arthritis was under control with the drug methotrexate, which Dr. Fradin had prescribed for Mr. Hamlet.

14. Prior to the events recounted below, Mr. Hamlet was in excellent physical condition and exhibited little, if any, sign of arthritis.

15. In or about April 2000, Dr. Fradin informed Mr. Hamlet that he considered Mr. Hamlet to be a good candidate for a clinical drug trial entitled "Study ACD2059g: Phase III Efalizumab in Adults with Moderate to Severe Plaque Psoriasis" ("the experiment"). The purpose of the experiment was to test the efficacy and safety of the experimental drug for patients with moderate to severe plaque psoriasis.

16. This experiment was a double blind, placebo-controlled, multi-center study sponsored by Genentech and XOMA. These defendants contracted with Parexel to conduct the study and with the WIRB to serve as the federally required

Institutional Review Board (IRB). "Placebo controlled" means the experiment tested the results of those receiving the experimental drug against subjects who received a placebo (i.e., a substance which the researchers knew was not therapeutic in any pharmochemical manner). "Double blind" in this context means neither the researcher nor the patient knows into which arm of the trial the subject has been randomized; in other words, neither the researcher nor the patient knew whether the patient was receiving the experimental drug or the placebo.

17. The experiment was unethical because the subjects randomized into the placebo arm would receive no treatment, despite the fact that an existing therapy was available. In giving such subjects a placebo, they were being subjected to the risk of suffering significant harm.

18. Upon information and belief, it was WIRB's duty, as the federally required IRB, to assist Genentech, XOMA and Parexel in developing protocols for the screening of individuals (a.k.a. subjects or patients) to ensure that individuals whose medical conditions would, or were likely to, substantially and/or permanently worsen if placed in the placebo arm of the experiment, would not be included as participants in the experiment. Mr. Hamlet, in that he suffered from psoriatic arthritis and not just psoriasis, was such an individual.

19. Upon information and belief, part of the experiment's protocol required that the subject discontinue methotrexate and/or other medications taken for their psoriasis 28 days before the first injection during his or her participation in the experiment.

20. Dr. Fradin informed Mr. Hamlet that Mr. Hamlet was a good candidate for the experiment, and Dr. Fradin told Mr. Hamlet that the experimental drug was very promising, offering fewer adverse effects than treatment with methotrexate.

21. Accordingly, on or about May 3, 2000, in anticipation of Mr. Hamlet's participating in the experiment, Dr. Fradin took Mr. Hamlet off of methotrexate, the drug that had been relieving and/or preventing Mr. Hamlet's psoriasis and arthritis symptoms and preventing further adverse development of the disease.

22. On or about June 1, 2000, Mr. Hamlet received from employees or agents of Genentech, XOMA or Parexel a copy of the Research Subject Information and Consent Form (the "April 13 consent form"), the contents of which had been approved by the WIRB for the experiment. (See Exhibit "A", which is attached hereto and incorporated herein.)

23. The April 13 consent form referred to Dr. Fradin as the investigator and/or the study doctor with respect to Mr. Hamlet's participation in the experiment.

24. Upon information and belief, Dr. Fradin was paid by Genentech, XOMA and/or Parexel for his role as investigator or study doctor for Mr. Hamlet in the experiment.

25. The April 13 consent form did not indicate that individuals diagnosed with psoriatic arthritis should not participate in the experiment.

26. The April 13 consent form indicated that the costs to treat medical problems that result from the experiment would not be reimbursed by Genentech.

27. Ultimately, at the request of Mr. Hamlet, the April 13 consent form was changed to provide that Genentech would "assume responsibility for the costs of immediate treatment of any adverse reaction or injury which, in the reasonable judgment of the study center and Genentech, specifically results from the investigational new drug, but only to the extent such expenses are not attributable to a failure to adhere to the terms of the protocol (study plan), to the negligence or misconduct of the study center or the investigator or to your preexisting abnormal medical condition. . . ."

28. On or about June 7, 2000, Dr. Fradin informed Mr. Hamlet that he (Dr. Fradin) would be present throughout the experiment to monitor Mr. Hamlet's condition as he had done for almost a decade as Mr. Hamlet's treating physician.

29. Dr. Fradin explained to Mr. Hamlet that the experiment was in its last stage and this was the least risky stage for participants since the primary focus of this stage of the experiment was the experimental drug's efficacy.

30. At no time during Mr. Hamlet's consideration of giving his consent to his participation in the experiment did Dr. Fradin or and employee or agent of the other defendants discuss with Mr. Hamlet the potential dangers or negative health implications to Mr. Hamlet of his receiving a placebo while a participant in the experiment.

31. At no time during Mr. Hamlet's consideration of giving his consent to his participation in the experiment did Dr. Fradin or and employee or agent of the other defendants discuss with Mr. Hamlet his risk of developing debilitating arthritis

as a result of his participation in the experiment.

32. Ultimately, relying upon the long and trusting relationship Mr. Hamlet had developed with Dr. Fradin, Mr. Hamlet was convinced by Dr. Fradin that he should participate in the experiment and that his participation in it would be beneficial to him. Mr. Hamlet believed that Dr. Fradin was continuing to act in Mr. Hamlet's best interests as his physician.

33. On July 11, 2000, Mr. Hamlet signed the revised version of the Research Subject Information and Consent Form (the "June 27 consent form") and, on the same day, he received his first injection in the experiment. (See Exhibit "B", which is attached hereto and incorporated herein.) The June 27 consent form did not indicate that individuals diagnosed with psoriatic arthritis should not participate in the experiment. Unknown to Mr. Hamlet, the injection he received was a placebo since that was the arm of the trial into which Mr. Hamlet had been placed.

34. By July 11, 2000, Mr. Hamlet had not taken any methotrexate for about 72 days, and his psoriasis had become so invasive that his arms, trunk and thighs were covered in unsightly plaques and large encrustations.

35. On August 4, 2000, Mr. Hamlet signed another revised version of the Research Subject Information and Consent Form (the "July 20 consent form") and, on August 16, 2000, Dr. Fradin signed the July 20 consent form as the investigator. (See Exhibit "B", which is attached hereto and incorporated herein as Exhibit "C.") The July 20 consent form did not indicate that individuals diagnosed with psoriatic arthritis should not participate in the experiment.

36. Mr. Hamlet went to Dr. Fradin's clinic, Chapel Hill Dermatology, to receive his injections and to be evaluated by Dr. Fradin during the experiment.

37. From July 11, 2000 through at least December 27, 2000, Dr. Fradin routinely examined Mr. Hamlet and collected extensive information regarding Mr. Hamlet's worsening skin condition; yet, Dr. Fradin did not advise Mr. Hamlet to withdraw from the experiment, nor did Dr. Fradin restart Mr. Hamlet's methotrexate prescription. In fact, Dr. Fradin encouraged Mr. Hamlet to remain in the experiment.

38. Dr. Fradin had the right, pursuant to the April 13, June 27 and July 20 consent forms, to find out from Genentech whether Mr. Hamlet was receiving the experimental drug or the placebo. At no time prior to December 28, 2000 did Dr. Fradin exercise that right.

39. On at least twelve scheduled visits during the experiment, Dr. Fradin recorded the extent of Mr. Hamlet's psoriasis and conducted a physical examination of Mr. hamlet as required by Genentech, XOMA and Parexel.

40. During the experiment, Mr. Hamlet's skin condition had worsened to the most extreme case it had ever been.

41. Throughout the experiment, both Ms. Nygard and Mr. Hamlet covered Mr. Hamlet's skin with lotion, futilely trying to abate the massive raw, partly bloody, dry patches all over his body.

42. From mid-July 2000 through at least December 2000, much of Mr. Hamlet's body was encrusted with psoriasis plaques, and his clothes were often stained with blood.

43. As Mr. Hamlet's condition worsened, he began to experience arthritic symptoms.

44. Throughout the experiment, Dr. Fradin reassured Mr. Hamlet that he could safely continue in the experiment without permanent effects and that he would regain his previously excellent health no matter how bad his skin became during the experiment.

45. In October 2000, Mr. Hamlet entered the second phase of the 3-phases of the experiment during which, rather than receiving injections of placebo, he received a less than therapeutic dose of the experimental drug.

46. During the aforementioned second phase, Mr. Hamlet's skin condition was minimally improved.

47. Still, on or about December 8, 2000, Mr. Hamlet's arthritis began to invade his lower spine, causing him to experience severe pain.

48. During the middle to late December 2000, Mr. Hamlet's arthritis worsened, invading his legs and rendering him unable to work and laying, making him mostly bedridden, and making it difficult for him to walk without the aid of a cane. By the end of December 2000, he was virtually unable to do anything due to the swelling and stiffness in his knees and lower legs.

49. On December 21, 2000, Mr. Hamlet received his last injection during his participation in the experiment. The study coordinator who performed the injection advised Mr. Hamlet that he should withdraw from the experiment. She told him that he had not been getting a full dose of the experimental drug and that he would not

be getting a full dose of the experimental drug for the remainder of the experiment, or words to that effect.

50. On December 21, 2000, Mr. Hamlet announced his intention to withdraw from the experiment and requested of Dr. Fradin that his methotrexate prescription be restarted. At that time the study coordinator requested that Mr. Hamlet attend the last day of the Extended Treatment Period on December 27, 2000 to complete paperwork. Mr. Hamlet did so. However, Mr. Hamlet received no further injections of either placebo or the experimental drug, and he did not participate in the experiment's final phase, the "Follow-Up Period."

51. Despite Mr. Hamlet's disabling condition and his request to have his methotrexate prescription restarted, Dr. Fradin did nothing to treat his patient's condition until early January 2001.

52. On or about January 3, 2001, at Mr. Hamlet's request, Dr. Fradin restarted Mr. Hamlet's methotrexate prescription. When the prescription was restarted, Mr. Hamlet was placed on a higher does of methotrexate than he had been taking immediately prior to his participation in the experiment.

53. Later, in January 2001, Mr. Hamlet developed a distended round lump that grotesquely bulged out from his right knee.

54. As a result of the withdrawal of Mr. Hamlet from his pre-existing drug therapy and the subsequent failure to timely treat Mr. Hamlet's psoriatic arthritis, Mr. Hamlet developed significantly worsened psoriasis, severe and debilitating arthritis which appears to be permanent in nature, pain and suffering, lost wages, and a loss

of earning capacity.

FIRST CLAIM FOR RELIEF: CLAIM OF NEGLIGENCE AGAINST DEFENDANTS GENENTECH, INC.; XOMA, LTD; WESTERN INSTITUTIONAL REVIEW BOARD, INC.; PAREXEL INTERNATIONAL, LLC; MARK FRADIN, M.D.; AND CHAPEL HILL DERMATOLOGY, P.A.

55. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

56. At all times mentioned herein and material hereto, the defendants, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to Mr. Hamlet, of properly and carefully examining him in order to determine his condition and eligibility for the experiment, of properly and carefully designing and administering the experiment's protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which Mr. Hamlet remained under said defendants' protocol, care and treatment.

57. As a result of the careless, negligent and reckless conduct of the defendants, Mr. Hamlet was caused to suffer severe pain and discomfort and ultimately suffered from permanent and debilitating arthritis.

58. Each of these defendants, jointly and severally, by and through their separate and respective agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

a. failing to properly and adequately evaluate Mr. Hamlet's condition

and eligibility for the experiment;

b. failing to perform proper and adequate testing for Mr. Hamlet's condition;

c. failing to properly and adequately treat and care for Mr. Hamlet's condition under all of the circumstances;

d. failing, in conducting the experiment, to perform proper and careful practices and procedures in accordance with the standards prevailing in the community in which defendants practiced and pursued pharmaceutical studies at the time;

e. failing to properly monitor Mr. Hamlet's condition both prior to and subsequent to the injection of the experimental drug and/or placebo into Mr. Hamlet;

f. failing to properly inform Mr. Hamlet of all the risks of the experiment so as to afford him the opportunity to make an informed decision as to his participation in the experiment;

g. failing to properly and timely observe, discover, diagnose, treat and care for Mr. Hamlet's condition after he became a participant in the experiment;

h. failing to design, implement and monitor the experiment in accordance with the ethical standards for such experiments;

i. failing to establish proper protocols or qualifying criteria for participation of subjects in the experiment;

j. failing to remove Mr. Hamlet from the experiment under

circumstances indicating he should have been removed from it;

k. failing to intercede in order to determine whether Mr. Hamlet had received the placebo;

l. failing to warn Mr. Hamlet regarding the danger of receiving placebo given Mr. Hamlet's pre-existing diagnosis of psoriatic arthritis;

m. failing to recognize that the methotrexate had been protecting Mr. Hamlet from both psoriasis and arthritis;

n. failing to recognize that Mr. Hamlet faced developing permanent arthritis injury; and

o. any other way shown by the evidence.

59. The negligence of the defendants, jointly and severally, was a direct and proximate cause of the above noted injuries, damages and losses sustained by Mr. Hamlet.

SECOND CLAIM FOR RELIEF: CLAIM OF BREACH OF FIDUCIARY DUTY BY DEFENDANTS GENENTECH, INC.; XOMA, LTD; WESTERN INSTITUTIONAL REVIEW BOARD, INC.; PAREXEL INTERNATIONAL, LLC; MARK FRADIN, M.D.; AND CHAPEL HILL DERMATOLOGY, P.A.

60. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

61. Defendants owed a fiduciary duty to Mr. Hamlet by virtue of the execution of the informed consent document and the establishment of a researcher-subject relationship.

62. This duty carried with it, among other responsibilities, the obligation to

provide Mr. Hamlet with the information needed to make an informed decision as to whether to participate in the experiment.

63. As fiduciaries, the defendants were obligated to act in good faith and with fair dealing toward Mr. Hamlet throughout his interactions and experiences with them.

64. In committing the negligent acts described above, the defendants breached their fiduciary duties toward Mr. Hamlet.

65. The breach of this fiduciary duty to plaintiff was a direct and proximate cause of the above noted injuries, damages and losses Mr. Hamlet.

THIRD CLAIM FOR RELIEF: COMMON LAW FRAUD AND INTENTIONAL MISREPRESENTATION BY DEFENDANTS GENENTECH, INC.; XOMA, LTD; WESTERN INSTITUTIONAL REVIEW BOARD, INC.; PAREXEL INTERNATIONAL, LLC; MARK FRADIN, M.D.; AND CHAPEL HILL DERMATOLOGY, P.A.

66. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

67. Defendants made the following intentional misrepresentations and committed common law fraud in:

a. upon information and belief, intentionally misrepresenting to Mr. Hamlet the risks of his participation in the experiment;

b. upon information and belief, in intentionally failing to adequately disclose the extent to which Dr. Fradin had a conflict of interest due to his contractual agreement with defendants Genentech, XOMA, WIRB and Parexel to provide subjects for the experiment and his duties and responsibilities as plaintiff's

physician; and

c. upon information and belief, in intentionally misleading Mr. Hamlet with assurances, during his participation in the experiment, that his worsening physical condition, including his developing arthritis, was curable.

68. The misrepresentations set forth above were done with the knowledge of these defendants that the misrepresentations were false, or that failure to provide information provided a false impression to Mr. Hamlet when made.

69. These misrepresentations constituted false representations or concealment of a material fact.

70. These misrepresentations were reasonably calculated to deceive Mr. Hamlet and were made with the intent to deceive Mr. Hamlet.

71. These misrepresentations did, in fact, deceive Mr. Hamlet and resulted in his agreement to become a subject in the experiment and then to continue to participate as a subject in the experiment despite his worsening condition.

72. Mr. Hamlet justifiably relied upon the misrepresentations set forth above in making the decision as to whether to participate in the experiment.

73. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, Mr. Hamlet participated in the experiment. This participation resulted in his above noted damages, injuries and losses.

FOURTH CLAIM FOR RELIEF: CONSTRUCTIVE FRAUD AGAINST DEFENDANTS GENENTECH, INC.; XOMA, LTD; WESTERN INSTITUTIONAL REVIEW BOARD, INC.; PAREXEL INTERNATIONAL, LLC; MARK FRADIN, M.D.; AND CHAPEL HILL DERMATOLOGY, P.A.

74. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

75. Due to their fiduciary position described above, all defendants were at an advantage, to the detriment of Mr. Hamlet.

76. Defendants worked a constructive fraud upon Mr. Hamlet in:

a. failing to adequately disclose to Mr. Hamlet the risks of his participation in the experiment;

b. failing to adequately disclose the extent to which Dr. Fradin had a conflict of interest in the study; and

c. making assurances to Mr. Hamlet, during his participation in the experiment, that his worsening physical condition, including his developing arthritis, was curable.

77. Mr. Hamlet made his decision to become a subject in the experiment, and remained committed to staying in the experiment, upon the assurances of all defendants, explicit or implicit, that doing so was consistent with his short-and long-term health interests. He relied on these assurances and had no independent information or advice to the contrary. The defendants worked a constructive fraud upon Mr. Hamlet.

78. As a result of the constructive fraud defendants worked upon Mr. Hamlet, he suffered the above noted injuries, damages, and losses.

FIFTH CLAIM FOR RELIEF: NEGLIGENT MISREPRESENTATION BY

DEFENDANTS GENENTECH, INC.; XOMA, LTD; WESTERN INSTITUTIONAL REVIEW BOARD, INC.; PAREXEL INTERNATIONAL, LLC; MARK FRADIN, M.D.; AND CHAPEL HILL DERMATOLOGY

79. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

80. The defendants negligently misrepresented facts that were highly relevant to Mr. Hamlet's decisions to participate in the experiment and to remain a subject in it.

81. Specifically, the defendants, by and through themselves or their agents acting on their behalf, negligently misrepresented to Mr. Hamlet:

a. That, under the circumstances of his prior medical history, he was an appropriate candidate for participation in the experiment;

b. That, under the circumstances of his prior medical history, the medical risks to his health were not substantial and potentially permanent; and

c. That, his worsening physical condition which was apparent as his participation in the experiment continued, including his developing arthritis, was curable.

82. These negligent misrepresentations were made with the knowledge that Mr. Hamlet would rely on these misrepresentations in making his decision to consent to participate in the experiment and in making his subsequent decisions to remain in the experiment.

83. Mr. Hamlet did reasonably rely on these misrepresentations and as a proximate cause of this reliance suffered the above noted injuries, damages, and

losses. The defendants are liable to Mr. Hamlet for negligent misrepresentation.

SIXTH CLAIM FOR RELIEF: NEGLIGENCE OF DEFENDANTS WESTERN INSTITUTIONAL REVIEW BOARD, INC.

84. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

85. It was the responsibility of the agents and employees of WIRB to approve the experiment in which Mr. Hamlet participated.

86. The agents and employees of WIRB who approved the experiment had a duty to protect Mr. Hamlet and other subjects from unethical research practices.

87. The agents and employees of WIRB were negligent in approving the design of the study, in approving the Research Subject Information and Consent Form, and in not appropriately monitoring the informed consent process and the conduct of the experiment.

88. The negligence of WIRB as herein alleged was a direct and proximate cause of the injuries, damages and loss of earning capacity sustained by Mr. Hamlet.

SEVENTH CLAIM FOR RELIEF: MEDICAL NEGLIGENCE AGAINST DEFENDANT MARK FRADIN

89. Plaintiff incorporates by reference all above paragraphs as if fully set forth herein.

90. At all times mentioned herein and relevant hereto, a physician-patient relationship existed between Dr. Fradin and Mr. Hamlet. As Mr. Hamlet's physician, Dr. Fradin had a fiduciary duty toward him. Given this relationship, Mr. Hamlet had

the right to place his trust and confidence in Dr. Fradin, and to trust that Dr. Fradin would do him no harm. In particular, Dr. Fradin had the duty to provide Mr. Hamlet with medical evaluation and treatment in accordance with the standards of practice among members of the same health care profession with similar training and experience and situated in the same or similar communities at that time.

91. In enrolling Mr. Hamlet in the experiment and overseeing his continued participation in it, Dr. Fradin failed to apply the degree of professional learning, skill, and ability which other dermatologists similarly situated ordinarily apply to their patients, failed to exercise reasonable care and diligence in the application of his knowledge and skills for Mr. Hamlet's benefit, and did not use his best judgment.

92. Dr. Mark Fradin was negligent in:

a. failing to properly and adequately evaluate Mr. Hamlet's condition and eligibility for the experiment;

b. failing to warn Mr. Hamlet regarding the danger of the administration of a placebo drug given Mr. Hamlet's arthritis;

c. failing to properly inform Mr. Hamlet of all of the risks of receiving placebo during his participation in the experiment so as to afford him the opportunity to make an informed decision as to his participation in the experiment;

d. failing to recognize and/or act on the knowledge that the methotrexate had been protecting Mr. Hamlet from both psoriasis and arthritis;

e. failing to recognize or to communicate to Mr. Hamlet that he faced or could face permanent arthritis injury from his participation in the study;

f. enrolling Mr. Hamlet in the experiment, despite the potential of this study to harm William Mr. Hamlet;

g. failing to properly and timely observe, treat and care for Mr. Hamlet's condition after he began to be a participant in the experiment;

h. failing to intercede in order to determine whether Mr. Hamlet had received the placebo;

i. failing to remove Mr. Hamlet from the experiment; and

j. any other ways shown by the evidence.

93. Dr. Fradin was negligent in failing to provide Mr. Hamlet with medical care that was in accordance with the standards of practice among other members of the same health care profession situated in the same or similar communities.

94. As a direct and proximate result of the negligence of Dr. Fradin, Mr. Hamlet sustained the above noted injuries, damages and losses.

EIGHTH CLAIM FOR RELIEF: CLAIM AGAINST DEFENDANT CHAPEL HILL DERMATOLOGY, P.A.

95. Plaintiff incorporates by reference the above paragraphs as if fully set forth herein.

96. Defendant Chapel Hill Dermatology is liable under respondeat superior for the negligence of Dr. Fradin.

97. Defendant Chapel Hill Dermatology had a duty to provide medical care to its patients, through its employees and agents, that was in accordance with the standards of practice among members of the same health care profession with

similar training and experience in the same or similar communities.

98. Defendant Chapel Hill Dermatology was negligent in failing to provide medical care to Mr. Hamlet that was in accordance with the standards of practice among other members of the same health care profession with similar training and experience situated in the same or similar communities.

99. As a direct and proximate result of the negligence of defendant Chapel Hill Dermatology, Mr. Hamlet sustained the above noted injuries, damages and losses.

PLAINTIFF DEMANDS A TRIAL BY JURY.

WHEREFORE, plaintiff prays:

1. That he recover of the defendants, jointly and severally, damages in excess of Ten Thousand Dollars ($10,000.00) in compensatory damages with costs and interest from the date this suit is instituted; and

2. That he has such other relief as the Court deems just and proper.

This the _____ day of July, 2003.

Anne R. Slifkin/Thomas R. Sparks
Becton, Slifkin & Bell, P.A.
4000 WestChase Blvd., Suite 500
Raleigh, NC 27607
(919) 755-1068

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

This is to certify that the foregoing Complaint and Demand for Jury Trial was served on the following individuals and/or entities by mailing it to the below-listed addressees via certified mail, return receipt requested, prepaid and addressed as follows:

Defendants:

Genentech, Inc., c/o its registered agent.
Corporation Service Company
327 Hillsborough Street
Raleigh, NC 27603

XOMA, Ltd., c/o its registered agent,
Christopher J. Margolin
2910 Seventh Street
Berkeley, California 94710

Western Institutional review Board, Inc., c/o its registered agent,
Angela Bowen
3535 7th Avenue SW
Olympia, Washington 98502

Parexel International, LLC, c/o its registered agent,
CT Corporation
225 Hillsborough Street
Raleigh, North Carolina 27603

Mark S. Fradin, M.D.
891 Willow Drive
Chapel Hill, North Carolina 27514

Chapel Hill Dermatology, P.A., c/o its registered agent
Stanley B. Levy, M.D.
891 Willow Drive, Suite 2
Chapel Hill, North Carolina 27514

This the _____ day of July, 2003.

Anne R. Slifkin/Thomas R. Sparks

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