NORTH CAROLINA DURHAM COUNTY	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION 1 CVS 4721
Richard Aiken, Jean K. Carroll, as Executrix of the Estate of Harold G. Carroll, Jean K. Carroll, Individually, Peggy Cox, as Administratrix of the Estate of Paul F. Cox, Peggy Cox, Individually, Helene L. Fligel, Jason Gannon, as Personal Representative of the Estate of Jennifer L. Gannon, John Haddock, as Executor of the Estate of Karen Heath, Walter Jacobs, as Executor of the Estate of Juliet J. Jacobs, Walter Jacobs, Individually, Polly Johnson, as Executor of the Estate of Malcom W. Johnson, and Polly Johnson, Individually, Plaintiffs vs. Duke University, Duke University Health System, Inc., Private Diagnostic Clinic, PLLC, Joseph Nevins, Ph.D., Anil Potti, M.D., Michael Cuffe, M.D., Sally Kornbluth, M.D., John M. Harrelson, M.D., and CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc, Defendants	**COMPLAINT** **(JURY TRIAL DEMANDED)**

DURHAM COUNTY FILED SEP 7 2011 4:03 O'CLOCK P.M. CLERK OF SUPERIOR COURT

The Plaintiffs, complaining of the Defendants, allege and say that:

I. PARTIES AND JURISDICTION

1. Plaintiffs, on behalf of their intestates and individually as applicable, are asserting claims jointly and severally against the Defendants in this civil action arising from their participation, under false pretenses, in a fraudulent clinical trial, exposure to improper and

unnecessary chemotherapy, and improper treatment of the plaintiffs' cancers based upon falsified medical research submitted to the United States government and its entities, various peer reviewed medical and scientific journals and to the wider public (hereinafter generally referred to as "fraudulent and dangerous clinical trials").

2. Plaintiffs' claims are based, in part, upon information and belief that all defendants have engaged in a systemic plan to develop for-profit cancer tests for the primary purpose of generating billions of dollars in revenue; and that rather than actively protecting the safety and rights of patients in proper clinical trials, they chose a path of conduct that was evasive, deceptive, misleading and fraudulent by falsely representing that the delivery of chemotherapy agents to human subjects was based on valid science, when in fact they either knew or should have known that it was not.

3. All allegations specific to the plaintiff patients and their plaintiff spouses, if applicable, including averments of residence, injuries, proximate cause, and claims for general damages and loss of consortium where applicable, are contained in the attached Exhibits # 1 through # 8, each of which are herein incorporated by reference as if fully set forth. All allegations that reference "Plaintiff" or "Plaintiffs" shall refer to and mean the plaintiff intestate as represented by the personal representative or the individual claimant, as applicable.

4. Defendant Duke University (hereinafter referred to as "Duke") is a North Carolina corporation with a principal office and place of business in Durham County, North Carolina. Duke University's registered agent for service of process is Pamela Bernard, Vice President and General Counsel, at 310 Blackwell Street, 4th Floor, Box 104124, Durham, North Carolina, 27710.

5. Duke University Health System, Inc. (hereinafter referred to as "DUHS") is a North Carolina corporation with a principal office and place of business in Durham County, North Carolina. DUHS's registered agent for service of process is Pamela Bernard, Vice President and General Counsel, at 310 Blackwell Street, 4th Floor, Box 104124, Durham, North Carolina, 27710. DUHS is a wholly owned and wholly controlled subsidiary of Duke University.

6. Defendants Duke and DUHS together hold and held themselves out to the public and the plaintiffs as "Duke Medicine," and claim that Duke Medicine provides 'extraordinary' and 'world-class' care to their patients. Defendant Duke is defendant DUHS's apparent agent and vice versa, and the two jointly and severally combined to tortiously injure the

plaintiffs and others similarly situated, causing the injuries alleged in the subsequent claims for relief incorporated by reference.

7. Upon information and belief, Defendant Private Diagnostic Clinic, PLLC is a Professional Limited Liability Company organized and operating under the laws of the State of North Carolina with its principal place of business in Durham County, North Carolina. Defendant Private Diagnostic Clinic, PLLC is in the business of providing professional medical services and care through its own facilities or those owned and/or operated by Defendant Duke University Health System, Inc., or the other corporate Defendants named herein.

8. Defendant Joseph Nevins, Ph.D. (herein after referred to as "Nevins") is a citizen and resident of Orange County, North Carolina and was at all times relevant to this Complaint an agent, servant, and employee of Duke University and/or DUHS and/or Duke Medicine, Private Diagnostic Clinic, PLLC, acting within the course and scope of his employment.

9. Defendant Anil Potti, M.D. (herein after referred to as "Potti") is a duly licensed physician within the state of North Carolina, and a citizen and resident of Orange County, North Carolina and was at all times relevant to this Complaint an agent, servant, and employee of Duke University and/or DUHS and/or Duke Medicine, and/or Private Diagnostic Clinic, PLLC, acting within the course and scope of his employment.

10. At all points in time during his work as a Duke cancer researcher and during the clinical trials, Potti was under the tutelage, control and supervision of his mentor Nevins, the director of the Duke Center for Applied Genomics & Technology, one of several centers under Duke University and/or DUHS and/or Duke Medicine and/or Duke Medicine's Institute of Genome Sciences and Policy (IGSP).

11. Defendant Michael Cuffe, M.D. (herein after referred to as "Cuffe") is a duly licensed physician with the state of North Carolina, and a citizen and resident of Orange County, North Carolina and was at all times relevant to this Complaint an agent, servant, and employee of Duke University and/or DUHS and/or Duke Medicine and/orPrivate Diagnostic Clinic, PLLC, acting within the course and scope of his employment.

12. Defendant Sally Kornbluth, M.D. (herein after referred to as "Kornbluth") is a duly licensed physician with the state of North Carolina, and a citizen and resident of Durham County, North Carolina and was at all times relevant to this Complaint an agent, servant, and

employee of Duke University and/or DUHS and/or Duke Medicine and/or Private Diagnostic Clinic, PLLC, acting within the course and scope of her employment.

13. Defendant John M. Harrelson, M.D., Chair of DUHS Independent Review Board (IRB), (herein after is referred to as "Harrelson") is a duly licensed physician with the state of North Carolina, and a citizen and resident of Durham County, North Carolina and was at all times relevant to this Complaint an agent, servant, and employee of Duke University and/or DUHS and/or Duke Medicine and/or Private Diagnostic Clinic, PLLC, acting within the course and scope of his employment.

14. Defendant CancerGuide Diagnostics, Inc. is a foreign corporation, formerly known as Oncogenomics, Inc., with its principal office and place of business at 280 S. Mangum Street, Suite 35D, Durham, 27701, Durham County, North Carolina. CancerGuide Diagnostics, Inc.'s registered agent for service of process is the Service Process Agent, North Carolina Secretary of State, Post Office Box 29622, Raleigh, North Carolina 27626-0622. Upon information and belief, CancerGuide Diagnostics, Inc. has carried out continuous and systematic contacts within the state of North Carolina since 2006, including but not limited to activities of its directors, officers and agents to capitalize on any financial gains realized by the Duke cancer researchers in the form of patents, clinical trials and other income generating activities.

15. Defendants Nevins, Potti, Cuffe, Kornbluth and Harrelson (the "Individual Defendants") were officers, agents, or employees of Duke University and/or DUHS and were acting on behalf of and for the benefit of Duke University and/or DUHS and/or Private Diagnostic Clinic, PLLC, at all times relevant in this Complaint, and were at all times relevant in this Complaint, acting in the course and scope of his/her employment and agency of Duke University and/or DUHS and/or Private Diagnostic Clinic, PLLC, .

16. Defendants Duke University and/or DUHS and/or Private Diagnostic Clinic, PLLC are liable for the negligence of the Individual Defendants and/or other officers, agents, employees, servants, staff or physicians under the doctrine of *respondeat superior*, the theory of agency, and/or the theory of corporate negligence, and the acts of negligence of the Individual Defendants and/or other officers, agents, employees, servants, staff or physicians are imputed to Duke University and/or DUHS and/or Private Diagnostic Clinic, PLLC.

17. Victor J. Dzau, MD, was appointed Chancellor for Health Affairs at Duke University and President and Chief Executive Officer of DUHS on July 1, 2004. In both capacities, Dzau reported and continues to report to the President of Duke University.

18. This Court has jurisdiction over this cause of action and personal jurisdiction over the defendants under N.C. Gen. Stat. §§ 1-75, 7A-240, 7A-243, and/or 1-75.4(1)(d).

19. Venue for this case is proper under N.C. Gen. Stat. Sec. 1-80 and 1-82.

20. The Defendants are properly joined in one action because the Plaintiffs assert against them rights to relief arising from the same series of events, negligent acts, and negligent omissions jointly, severally, and in the alternative, and because many questions of law and fact common to all Defendants will arise in the action.

II. FACTS
The Institute of Genome Sciences and Policy and Defendants Nevins and Potti's connection to Duke

21. Many of the following allegations have been widely reported and disseminated throughout the public domain by virtue of publication in respected academic journals and/or well-known media outlets, and as such the truth of all of the following allegations are plead upon good faith information and belief.

22. In 2003, the Institute of Genome Sciences and Policy (IGSP) was founded by Duke University. Included within the Duke ISGP was the Center for Applied Genomics & Technology. At all times relevant to the issues raised in this Complaint, the ISGP and the Center for Applied Genomics & Technology were entities of Duke University and/or DUHS .

23. From the outset, Defendant Joseph Nevins, Ph.D. was the director of the Center for Applied Genomics & Technology.

24. Defendant Anil Potti, M.D. joined Duke University and/or DUHS under the control and supervision of Defendant Nevins, in 2003.

25. Nevins cosigned grant applications and co-authored papers with Potti that were published in National scientific and medical journals.

26. In a 2007 IGSP newsletter, Potti was described by Duke as an oncologist acting as an Assistant Professor in the Duke IGSP and the Department of Medicines Division of Medical Oncology, and was identified by Duke as a former Rhodes Scholar who collaborated

closely with Nevins, the director of the IGSP's Center for Applied Genomics & Technology and Dr. Geoffrey Ginsberg, director of the IGSP's Center for Genomic Medicine.

Publication of Potti and Nevins' "Ground-Breaking" Cancer Research, and the Defendants' Initial Notice of the Flawed Science

27. In August 2006, Potti and Nevins along with other members of Duke University and/or DUHS including, Holly K Dressman, Ph.D., Michael Kelly, M.D., Geoffrey S. Ginsberg, M.D., PhD, Mike West, PhD. and David H. Harpole, Jr., M.D. published an article in the New England Journal of Medicine ("NEJM article") entitled "A Genomic Strategy to Refine Prognosis in Early-Stage Non–Small-Cell Lung Cancer" N Engl J Med. 2006 355:570-80.

28. In the NEJM article, the authors claimed to have developed a new prognostic model (the Lung Metagene Score ["LMS"] method) that could predict which lung cancer patients were likely to experience a tumor recurrence, and would thus benefit from chemotherapy as opposed to solely observation. The NEJM article summarized the results of a microarray analysis study the authors had conducted using profiles of tumors from early stage "non-small cell lung cancer" patients (NSCLC).

29. In July of 2006, Potti and Nevins along with other members of Duke University and/or DUHS including, Holly K Dressman, Ph.D., Michael Kelly, M.D., Geoffrey S. Ginsberg, M.D., PhD, PhD. and David H. Harpole, Jr., M.D., submitted for publication in the journal "Nature Medicine" a second article entitled "Genomic Signatures to Guide the Use of Chemotherapeutics." Although not published until November 2006 (Nat Med. 2006 12:1294-300), this article claimed that the microarray analysis discussed in the above-mentioned NEJM article could also be used to predict response to chemotherapy. In other words, the authors publicized that they had found genetic markers that could be used to predict a person's response to a specific type of chemotherapy.

30. Potti and Nevins' LMS method reported in the NEJM article was an experimental biomarker test designed to identify cancer patients who may be at high risk of disease recurrence, and was distinct from their genomic microarray analysis designed to predict actual chemotherapy sensitivities in individual patients as described in the "Nature Medicine" article above. At the time the NEJM article and the "Nature Medicine" articles were published,

these findings, if valid, would have been ground breaking in the field of cancer therapy and treatment.

31. On August 9, 2006, Duke Medicine's News and Communications Office released a press statement noting "The [Lung Metagene Score] test's promising results have initiated a landmark multi-center clinical trial, to be led by Duke Investigators next year. Patients with early-stage non-small cell lung cancer, the most common and fatal form of cancer, will receive the genomic test and its results will determine their treatment."

32. At some time soon after the publication of the NEJM and "Nature Medicine" articles, Nevins, Potti and Duke University and/or DUHS prepared to conduct clinical trials based upon the research described in the articles. Essentially, the Duke cancer researchers would test their theoretical findings on individual patients who had been diagnosed with cancer in a trial study.

33. In November of 2006, Potti, Nevins, Dr. Geoffrey Ginsburg and Judd Staples formed Oncogenomics, Inc. to capitalize on any financial gain resulting from the alleged cancer breakthrough research referenced above. Mr. Staples was, and remains today, the Director of Transitional Initiatives at Duke University Medical Center. Dr. Geoffrey Ginsberg was, and remains today, the director of the Center for Genomic Medicine within the Duke University IGSP.

34. Prior to the publication of the NEJM article in August of 2006, Potti approached one of his colleagues with a request to use another groups' research in an attempt to test Potti's Lung Metagene Score ("LMS") method on unpublished research data regarding primary lung adenocarcinomas conducted by an unrelated National Cancer Institute (NCI) Director's Challenge Consortium (DCC).

35. The colleague whom Potti approached regarding his request for unpublished research data for LMS testing communicated the request to David Beer, M.D., a genome scientist and professor of surgery and radiation oncology at the University of Michigan, because Dr. Beer was an investigator with the NCI DCC.

36. Dr. Beer agreed that Potti could use the unrelated, unpublished data to test the LMS but only after Dr. Beer's group had published the data through the NCI DCC.

37. After the above-mentioned NEJM article was published in 2006, Dr. Beer realized that Potti had used part of the NCI DCC's unpublished, unrelated data without Beer's

permission, that Potti, Nevins, the other Duke researchers and Duke University and/or DUHS had improperly obtained the NCI DCC's data and that the analysis within the NEJM article was highly suspect.

38. Dr. Beer contacted both the editor of the NEJM and Nevins, the Director of the Duke IGSP, and informed them that Potti had improperly obtained his group's data and the NEJM analysis was highly suspect.

39. After reading the 2006 NEJM article, Dr. Beer concluded that there were numerous errors in the NEJM article and numerous errors in the clinical data as listed in the NEJM article because he had personally conducted some of the research from which the clinical data was generated. He recognized that this was flawed science and placed Nevins on notice of same in 2006.

40. After being placed on notice of Potti's highly unethical research behavior and that the published NEJM article may be potentially flawed, Nevins took no action at that time to correct the NEJM article or to ensure that the scientific research upon which it was based, which had been publicly disseminated, was not flawed. Instead, Nevins communicated to the editor of the NEJM that he did not want to retract the 2006 NEJM article.

41. No adequate corrective action was taken by Potti, Nevins or by anyone at Duke University and/or DUHS to correct the numerous errors in the clinical data or research propounded by the Duke cancer researchers in the 2006 NEJM article.

42. After being informed that the 2006 NEJM article authored in part by Nevins improperly included material and potentially flawed scientific analysis, Nevins, Duke University and/or DUHS implicitly took part in the publication of the fraudulent, faulty research put forward by Potti by deciding not to retract or issue a corrective statement regarding the 2006 NEJM article, and thereby ratifying on their own behalf the prior wrongdoing of Potti.

43. At the time that the NEJM article was published in 2006, Potti, Nevins, other Duke researchers, and Duke University and/or DUHS knew or should have known that Potti's science was faulty. They knew or should have known that they had caused fraudulent and faulty scientific information to be published.

44. On September 28, 2006, Nevins and Johnathan M. Lancaster filed U.S. Patent Application no. 11/541,165 for "Individualized Cancer Treatments." The documentation lists as assignees the University of South Florida and Duke University. This patent was eventually

rejected in a non-final rejection by the U.S. Government in 2009 because of insufficient information. The non-final rejection informed Nevins and Mr. Lancaster of the issues resulting in the rejection and allowed an attempt to address them; however, they did not provide the gene expression profiles requested by the U.S. Government, and as a result no patent was approved.

Repeated Notice to Duke Defendants from the Scientific Community, And Duke's Abject Failure to Respond Appropriately

45. In 2006, two researches at The University of Texas MD Anderson Cancer Center, Keith A. Baggerly, PhD ("Baggerly") and Kevin R. Coombes, PhD ("Coombes"), set out to reproduce Potti and Nevins' research results in order to help investigators at MD Anderson use the approach.

46. In their attempt to reproduce the results, Baggerly and Coombes used the same data published by Potti and Nevins and additional information supplied by them in the 2006 "Nature Medicine" article regarding the methods, lists of cell lines (called sensitive or resistant), and the software used to perform the analysis. Baggerly and Coombes found themselves unable to reproduce the findings of the authors in the 2006 "Nature Medicine" article.

47. In 2006, Potti and Nevins were made aware of errors in the gene lists they published as part of their original research. In response to this notice, Potti communicated that a "list of gene errors" was fixed on their Duke research website, and the correct data was now available to other researchers trying to replicate the study results but there were other mistakes in the research.

48. On November 8, 2006, Drs. Baggerly and Coombes first emailed Nevins and Potti with questions and concerns regarding the published data.

49. On November 21, 2006, Potti responded to Baggerly and Coombes's November 8, 2006 email saying, "One thing is for sure, all data were analyzed the same way, using binary probit modeling methods, and the selection of genes which we have repeated a few times fairly consistent."

50. November 21, 2006, Potti denied any problem with the reproducibility of his findings in his reply to Baggerly and Coombes.

51. Baggerly and Coombes had supposedly been given access to all of the research data upon which the Duke research was based, and, as a result, they should have been able to verify at least the same statistical details found by Potti, Nevins and the Duke cancer researcher team. Despite this, Baggerly and Coombes, themselves respected researchers at the MD Anderson Cancer Center, continued to work on verifying these findings through 2007, yet remained unable to reproduce Potti and Nevins' results.

52. In the fall of 2006 and continuing throughout 2007, the MD Anderson researchers were issuing warnings to Nevins, Potti and to Duke University and/or DUHS both personally and in publications that the underlying scientific research was faulty. These warnings put, or should have put, Nevins, Potti, Duke University and/or DUHS on notice that any trials based on the scientific research could be putting patients at risk by exposing them to potentially ineffective or dangerous treatments.

53. Throughout 2007, Potti and Nevins were placed on continued notice of the ongoing concerns raised by Baggerly and Coombes, researchers at the MD Anderson Cancer Center.

54. On April 25, 2007, Baggerly and Coombes sent to Nevins and Potti a draft of an article they intended to publish in "Nature Medicine" in an effort to further place Nevins and Potti on notice of their growing concerns with the Duke research and its possible errors.

55. On April 30, 2007, Nevins and Potti responded to Baggerly and Coombes' April 25, 2007 draft article by saying, in part, "Regardless, we recognize this should be as complete as possible although I will say that this is likely a fault of many such studies and not limited to genomic/computational studies."

56. On April 30, 2007, Nevins and Potti once again denied any particular problem with the Duke research when Nevins responded to Baggerly and Coombes in an email, denying serious underlying problems with the "Nature Medicine" article.

57. In June 2007, Baggerly and Coombes submitted their article for publication to "Nature Medicine," the same article submitted in draft to Nevins and Potti weeks earlier.

58. Earlier, on November 1, 2006, Nevins and the Duke IGSP contacted the FDA seeking pre-Investigational Device Exemption ("pre-IDE") approval of the experimental LMS method study developed by Duke. The protocol submitted by Nevins and the Duke IGSP was to become the basis of the clinical trials at issue.

59. Most clinical trials involving investigational devices that pose "significant risk" to patients per FDA guidelines are submitted to the FDA for full IDE approval before the trials begin. Researchers and sponsors of clinical trials are encouraged by the FDA to submit protocols early via the "pre-IDE" approval process, because such early interaction with the agency should help to increase the researcher and/or sponsor's understanding of FDA requirements, regulations, and guidance documents, and will allow FDA personnel to familiarize themselves with the new technologies. This, in turn, can speed up the regulatory process of final IDE approval.

60. On January 19, 2007, Nevins and the Duke IGSP received a response to their pre-IDE submission in the form of a "Memorandum" from Dai J. Li, M.D., Ph.D., a medical officer with the FDA/OIVD/DIHD/IMDB.

61. Dr. Li made specific note of the fact that the study for which Nevins and the Duke IGSP had submitted the protocol for pre-IDE approval had not yet started, and the FDA provided biostatistical, analytical and clinical comment on the proposed protocol.

62. In the Memorandum, the FDA pointed out that the pre-IDE submission by Nevins and the Duke IGSP contained insufficient information and data. The FDA made numerous comments and suggestions to this effect; however, there is no indication that Nevins or the Duke IGSP made any changes to their protocols after receipt of the January 19, 2007 Memorandum.

63. There is no indication that Nevins or the Duke IGSP later sought final IDE approval from the FDA for the clinical trials conducted by Duke University and/or DUHS.

The Clinical Trials Begin: Duke Defendants' Decision to Push Forward and Capitalize on Research in the Face of Repeated Notice of Flawed Science

64. Beginning in 2007, Potti , Nevins, Duke University and/or DUHS began to apply for grants from various organizations to complete clinical trials based upon the Duke cancer research.

65. In written applications for millions of dollars in grant money to propel the Duke research, Potti knowingly, willfully and fraudulently lied and included false and fraudulent information which Nevins, Duke and/or DUHS knew or should have known was untrue, false and fraudulent information.

66. All of these fraudulent and deceptive applications were made by Potti while in the course and scope of his employment and/or agency with the rest of the Duke Defendants, and while under the direct supervision of his research director, Defendant Nevins, who knew or should have known, was untrue, false and fraudulent information.

67. In a July 2007 application to the American Cancer Society (ACS) for a grant, Potti claimed the following accolades and professional experience: "Rhodes Scholar" 1995, "Research Fellowship" with mentor Gordon McLaren at the Queensland Research Institute in Australia 1995-1996, National Merit Scholar 1989, and 2004 Clinical Research Scholar with the American Society of Hematology. All of these accolades and experience were false and fraudulent. Potti, Nevins, Duke University and/or DUHS knowingly, willfully and fraudulently misled the ACS with the inclusion of this false material.

68. Potti, Nevins, Duke University and/or DUHS received approximately $675,000 in grant money from the ACS based, in part, upon Potti's false application and the flawed scientific research conducted and published by the Duke cancer researchers.

69. In his 2007 application to the U.S. Department of Defense (herein after referred to as U.S. DoD) for a grant or sponsorship, Potti claimed the following accolades and professional experience: "Rhodes Scholar" 1995 and "Research Fellowship" at Queensland Research Institute in Australia 1995-1996 allegedly "studying the cardiac effects of malaria and betathalassamia/HgbE disease in south-east Asians under mentor Dr. Gordon McLaren. All of these accolades and experience were false and fraudulent. Potti, Nevins, Duke University and/or DUHS knowingly, willfully and fraudulently misled the U.S. DoD with the inclusion of this false material.

70. Potti, Nevins, Duke University and/or DUHS received grant money from the U.S. DoD to conduct clinical trials to determine if the genetic profiles could be used to successfully predict which chemotherapy agents would work best on patients. Essentially, Potti, Nevins, Duke University and/or DUHS received grant money from the U.S. DoD based, in part, upon Potti's false application and the flawed scientific research conducted and published by the Duke cancer researchers.

71. During the spring of 2007, Duke University and/or DUHS were planning, preparing and scheduling human subject trials to "test" the clinical efficacy of the experimental methods produced by Potti, Nevins and the Duke cancer researchers.

72. At this time, Duke University actively sought out corporations and companies interested in "commercializing a novel and versatile panel of genomic predictors of chemotherapy response." In its description of the clinical trials based upon the genomic predictors model, Duke University advertised, "a majority of the patients [in the clinical trials] have at least one treatment option with a high predicted probability of response."

73. In May 2007, after being placed on notice of the flawed science underlying the its cancer studies as referenced above, Duke University and/or DUHS nevertheless began their first clinical trial based upon the research in the Duke cancer researchers' articles. This was NCT00509366 Stage IIIB/IV Non-Small Cell Lung Cancer; brief title "Study Using a Genomic Predictor of Platinum Resistance to Guide Therapy in Stage IIIB/IV Non-Small Cell Lung Cancer (TOP0602)" (hereafter as "Lung Cancer Clinical Trial 1").

74. In September, 2007, Nevins, Potti, Harpole, Mike West, and Holly Dressman filed U.S. Patent Application no. 12/302,458 "Prediction of Lung Cancer Tumor Recurrence." The documentation lists no assignees.

75. Throughout the spring, summer and fall of 2007, Nevins, Potti and the Duke Defendants continued to publicize their "ground-breaking" research. On October 1, 2007, Potti and others at Duke University published yet another academic article promoting the same flawed research entitled "Pharmacogenomic Strategies Provide a Rational Approach to the treatment of Cisplatin-Resistant Patients with Advanced Cancer" in volume 26, number 28 of the Journal of Clinical Oncology.

76. Based on the notice of statistical errors and flaws in the underlying research as referenced above, by October 10, 2007, Potti and Nevins had published two corrections (aka "corrigenda") to the "Nature Medicine" article they had originally published in 2006.

77. These corrigenda were described by Potti and Nevins as only minor error corrections, and they continued to publicly deny that their 2006 published results were inherently flawed or scientifically unreliable.

78. On October 19, 2007, Nevins, Potti and Johnathan Lancaster filed for a second patent of the Duke research, U.S. Patent Application no. 11/975,722, entitled "Predicting Responsiveness to Cancer Therapeutics." This patent was part of the information used in the clinical trial at issue, as discussed more fully below. This patent application was rejected by U.S.

Patent Office, in part, because Potti, Nevins and Lancaster failed to supply sufficient data on the DNA sequences, called "probe sets," that had been used in the prediction model.

79. Sometime in October 2007, Duke University and/or DUHS began their second clinical trial based upon the flawed research in Potti and Nevins' cancer research articles. This was NCT00545948 Early Stage Non-Small Cell Lung Cancer (TOP0703); brief title "Adjuvant Cisplatin with Either Genome-Guided Vinorelbine or Pemextred for Early Non-Small Cell Lung Cancer (TOP0703)" (hereafter as "Lung Cancer Clinical Trial 2").

80. In November 2007, Baggerly and Coombes again attempted to place Nevins, Potti and Duke University and/or DUHS on notice of the numerous flaws in the genomic research by submitting a letter to the "Nature Medicine." This notice letter, entitled, "Microarrays: Retracing Steps," was published in the November 2007, Volume 13, Number 11 of "Nature Medicine." The letter pointed out glaring errors and numerous problems in the Duke cancer researchers' articles and in their research. Contrary to Potti and Nevins' early claim that these were only "minor errors," Baggerly and Coombes explained that the errors compromised the scientific integrity of the entire study, saying that the published "predictions are poor" and "[s]imulations show that the results are no better than those obtained with randomly selected cell lines." In essence, this was not the cancer breakthrough that these Defendants had repeatedly advertised.

81. After publication of Baggerly and Coombes notice letter in "Nature Medicine" in November 2007, the Duke Defendants did not suspend or terminate either of the clinical trials referenced above. Instead, they made the decision to continue both clinical trials and recruit more human subjects for testing.

82. In response to the above notice letter from Baggerly and Coombes, Potti and Nevins sent their own letter for publication in the 2007 issue of "Nature Medicine" to yet again defend the numerous errors reported in their research and made reference to certain data being blinded, therefore representing and claiming that they did not have information about the participants and results and thus were blinded to information. A blinded study is considered to be more reliable.

83. The statement that the datasets were blinded was completely untrue, an obvious misrepresentation and attempt to discredit the opinions of Baggerly and Coombes; the

false statement was uncovered in the October 23 issue of the Cancer Letter. (See allegation in paragraphs 93-95 infra)

84. Throughout 2007, Baggerly and Coombes were clearly issuing warnings both personally to Nevins and Potti, and to Duke University and/or DUHS and in publications that the clinical trials being conducted were based on questionable scientific research. These warnings put, or should have put, Nevins and Potti, and Duke University and/or DUHS, on notice that the trials could be putting patients at risk by exposing them to potentially ineffective and/or dangerous treatments.

85. On February 2, 2008, Baggerly and Coombes contacted Potti yet again with concerns over the research, this time with targeted questions about the "Lancet Oncology" article – authored in part by Potti – that both Potti and Nevins had cited in their November 2007 "Nature Medicine" response letter referenced above.. Potti again refused to consider the implications of Baggerly and Coombes' concerns, as evidenced in their responsive e-mail, "I am sorry if I am being totally honest, but I hope you understand our hesitation in indulging in another discourse on a similar topic with your group."

86. Throughout 2008, the MD Anderson researchers clearly issued warnings to Nevins, Potti and to Duke University and/or DUHS both personally and in publications that the clinical trials being conducted were based on questionable scientific research. These warnings put, or should have put, Nevins, Potti, Duke University and/or DUHS on notice that the trials could be putting patients at risk by exposing them to potentially ineffective or dangerous treatments.

87. In April of 2008, Duke University and/or DUHS began their third clinical trial based upon the research in the Duke cancer researchers' articles. This was NCT 00636441 Early Stage Breast Cancer; brief title "Trial to Evaluate Genomic Expression Profiles to Direct Preoperative Chemotherapy in Early Stage Breast Cancer" (hereafter "Breast Cancer Clinical Trial").

88. During each of the three trials in 2007 and 2008, Duke University and/or DUHS enrolled patients with the relevant type of lung or breast cancer, despite having notice of the flawed research as referenced above.

89. Sometime in May to June 2009, Baggerly and Coombes learned that the clinical trials based upon the flawed Duke cancer research papers were already underway in Lung Cancer

Clinical Trials 1 and 2, and Breast Cancer Clinical Trial (hereafter collectively "clinical trials at issue").

90. In September 2009, Baggerly and Coombes sent Duke University and/or DUHS a copy of an article that they intended to publish in the "Annals of Applied Statistics" which was intended to place them on notice yet again of the numerous problems and errors in the Duke cancer research which called into question the safety and efficacy of the clinical trials at issue.

91. In mid-September Baggerly and Coombes published their critiques in the "Annals of Applied Statistics" and stated, inter alia, "[p]atients in clinical trials are currently being allocated to treatment arms based on these results. However, we show in five case studies that the results incorporate several simple errors that may be putting patients at risk."

92. In the October 2, 2009 issue of "The Cancer Letter", volume 35, no. 36, Baggerly and Coombes summarized the critiques they published in the "Annals of Applied Statistics" as follows: (1) In the breast cancer trial all of the "labels" were reversed such that the results should be reversed. The MD Anderson researchers found that "slightly less than half of the data labels are wrong." (2) In the trial involving pemetrexed and cisplatin, the training data labels were also reversed. Both of the data labeling errors in the lung cancer and breast cancer clinical trials "could put patients at risk". (3) In the trial involving pemetrexed and cisplatin, all of the genes reported for the cisplatin signature were wrong, meaning, in essence, that the researchers were looking at the wrong row of data.

93. Despite this targeted and repeated notice of research errors and potential clinical trial dangers to Duke by Baggerly and Coombes, respected cancer researchers at the MD Anderson Cancer Center, in the October 2, 2009 issue of "The Cancer Letter," Potti and Nevins again denied any cause for concern, stating, "[w]e stand by our work…Yes, we have made mistakes, and, actually, we've learned from those mistakes. Because we recognized that the mistakes were manual mistakes – mistakes of cut-and-paste – we have automated the entire process."

94. In the same October 2, 2009 interview with "The Cancer Letter," Potti and Nevins claimed again that "Data was made available to us, blinded," and that the results reported in the "Lancet Oncology" article had been independently validated by the European Organization for Research and Treatment of Cancer (EORTC).

95. If Potti and Nevins had actually been able reproduce their research results using blind data sets, this would have been an important step in convincing Baggerly, Coombes and the rest of the scientific community that their "ground-breaking" results were reliable.

96. Contrary to Potti and Nevin's claim of blinded data set validation, Mauro Delorenzi, the head of the EORTC, unequivocally challenged Potti and Nevin's assertion in the October 23, 2009 issue of "The Cancer Letter," stating that the study as reported in the "Lancet Oncology" article was not, in fact, blinded, and furthermore that the EORTC was not able to reproduce Potti and Nevins results with the information they had been given.

97. Despite the September 2009 publication of targeted critiques by Baggerly and Coombes in the "Annals of Applied Statistics," Potti, Nevins and the Duke Defendants again chose to continue all three clinical trials at issue in full.

98. In the same October 2, 2009 issue of "The Cancer Letter," Dr. David Beer, professor of surgery and radiation oncology at the University of Michigan who had also tried unsuccessfully to replicate the Duke research results, highlighted the same issues and concerns raised by Baggerly and Coombes. Dr. Beer stated, "While some could be excused, the extent of these details is truly disturbing....Basing a clinical trial and treating patients using this data, and given the concerns they raise, is extremely risky. The authors and funding agencies must be held accountable."

Top Duke Administrators, Deans and Leadership Actively Work to Cover Up the Flawed Research and Continue the Clinical Trials

99. On September 22, 2009, Dr. Jeff Abrams, Associate Director of Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute ("NCI") contacted the leadership of Duke University and/or DUHS, to express concerns regarding the genomic predictors developed by Drs. Potti and Nevins.

100. Dr. Abrams referenced the Annals of Applied Sciences article, which came to NCI's attention during the course of NCI's review of a protocol submitted for CTEP review. He noted that the Baggerly/Coombes paper documented numerous instances of data errors and inconsistencies in a strikingly large number of publications originating from the research of Drs. Nevins and Potti over a period of several years.

101. Dr. Abrams indicated that NCI had been able to confirm some of the reported discrepancies by comparing information in published papers to information Duke had submitted to NCI about the same predictor models that had been submitted to NCI for review, and that given the large number of issues raised, it would be prudent to more fully investigate the reliability and credibility of the series of genomic predictors published and promoted by this team of Duke investigators.

102. In response to the patient safety concerns and flawed research issues raised by CTEP/NCI, the Duke Defendants claimed to launch a genuine investigation and independent review of the Duke research and methodology.

103. The entire plan and response developed by Duke University and/or DUHS was overseen and vetted by Dr. Nancy Andrews, Dean of the School of Medicine and Dr. Victor Dzau Chancellor for Health Affairs at Duke University and President and Chief Executive Officer of DUHS.

104. The persons selected by Duke University and/or DUHS to oversee the implementation of an independent review panel were Dr. Michael Cuffe, Vice Dean for Medical Affairs, Duke School of Medicine and Dr. Sally Kornbluth, Vice Dean for Research at Duke University School of Medicine who reported and report to Dr. Nancy Andrews, Dean of the School of Medicine.

105. Dr. Nancy Andrews, Dean of the School of Medicine, is married to Bernard Mathey-Prevot, MD, a Professor in Pediatrics at the Duke School of Medicine, and a Duke researcher whose career is tied closely with Nevins and Potti as a result of past collaboration with Nevins and recent, national journal publication with Nevins and Potti.

106. The persons selected by Duke University and/or DUHS to oversee the implementation of the independent review panel were under apparent conflicts of interests, as a result of their close involvement and leadership positions within the Duke School of Medicine as referenced above.

107. The Duke Defendants chose not to delegate oversight of the independent review panel to the university president and board of trustees who could take charge with outside investigators and scientists.

108. At all times relevant to this lawsuit and more particular in 2009, Dr. Andrews, Dr. Dzau, Dr. Cuffe, Dr. Kornbluth, Dr. Harrelson and Dr. Mathey-Prevot were employees,

agents and/or servants of Duke University and/or DUHS acting within the course and scope of his or her employment.

109. The Duke Defendants, through the Duke Institutional Review Board ("IRB") that was established to review all clinical trials including these, decided to have several statisticians review the validity of Potti and Nevins' underlying science, but did not include in the group persons with the necessary expertise to review the laboratory protocols and data handling methodology.

110. It was not until the early part of October, 2009 that Duke University and/or DUHS finally suspended enrollment in the three clinical trials. However, the Duke Defendants chose not to terminate the clinical trials, and instead allowed those patients already receiving treatment to continue in the trials, despite the fact that Duke was on notice of serious questions raised by Baggerly, Coombes, Dr. David Beer, and the CTE/NCI with regard to the science and to the safety to patients of being exposed to chemotherapy based on invalid science.

111. In early November, while the investigation was underway, the Duke Defendants posted on the genome website maintained by the University supplementary data that was in relation to the above-referenced Journal of Clinical Oncology paper – authored in part by Potti – previously published in October 2007 regarding the cisplatin and pemetrexed chemotherapy sensitivity signatures.

112. On November 9, 2009 Baggerly sent copies of his analysis of the above-referenced supplementary data posted by Duke to Dr. Sally Kornbluth. The e-mail placed Dr. Kornbluth on notice of two primary areas of concern – that the pemetrexed signature was reversed, and that all 59 validation samples of ovarian cancer samples were incorrectly labeled.

113. Dr. Baggerly was informed that this material would be sent to the Duke IRB for use in the review and investigation process.

114. In mid-November, 2009 Duke University and/or DUHS removed the above-referenced data set information and decedent pages from its website. When these pages reappeared in early April 2010, the web site for the Nature Medicine paper no longer contained gene lists or numerical data, but did contain the following comment: "please note that the published gene lists have errors, please contact authors for clarification." Similarly, the web site for the Nature Medicine paper no longer contained any supplementary files, just the following comment: "We apologize for any inconvenience caused. Please contact us for clarification."

115. No valid data Nature Medicine paper existed and/or was ever posted by Potti, Nevins, Duke University and/or DUHS.

116. Duke University and/or DUHS , along with both Potti and Nevins, knew or should have known that the data was corrupted, false, flawed, inaccurate, and fraudulent given that no independent group was able to reproduce their research results or successfully apply an algorithm to an independent data set.

117. The review panel established by the Duke IRB was not asked to perform an exhaustive and thorough investigation and review, from the very beginning, the processes and the methodologies used in the underlying Duke research.

118. The review panel established by the Duke IRB was asked only to address two narrow questions: "1. Have the methodology errors originally communicated by the MD Anderson Cancer Center researchers, Baggerly and Coombes, been adequately addressed by the Duke researchers," and "2. Do the methods as originally developed and as applied in the context of these trials remain valid?"

119. The above-referenced external review began in mid-October, and the Defendants should have given the external review panel unfettered access to all of the data, software, analysis and other information needed without the interference, influence and bias of Nevins, Potti and other members of Duke University and/or DUHS.

120. Despite the fact that the recent information sent by Baggerly and Coombes was not only available, but also critical to any determination to be made by the "external panel," Defendants Cuffe and Kornbluth, in consultation with defendant, Harrelson, decided not to make this relevant information available to the "external panel".

121. Defendants Cuffe, Kornbluth and Harrelson knew or should have known that Duke would base its decisions regarding the future of the clinical trials at issue, in part, on the determination of the "external panel" and those decisions would greatly affect the lives of the participants to the clinical trials as well as greatly affect the pecuniary interests of Duke and the financial success of the clinical trials.

122. Defendants Cuffe, Kornbluth and Harrelson knew or should have known there was a possibility of misconduct with the cancer research upon which the clinical trials had been based, yet, they purposely withheld some of the MD Anderson researchers' questions and critiques from the "external panel" and the remaining members of the IRB.

123. As Chair of the IRB, Defendant Harrelson had an independent, non-delegable duty to act properly, with fairness and within the protocols of the Belmont Report as adopted by the U.S. Government into federal law pursuant to 45 C.F.R. Part 46, including the adoption by the U.S. DoD.

124. On December 22, 2009, the "external panel" provided a written report of its findings to the Duke IRB.

125. Defendants Michael Cuffe, MD, Vice Dean of Medical Affairs at Duke University School of Medicine, and Sally Kornbluth, Vice Dean for Research at Duke University School of Medicine published a letter online January 29, 2010 in "the Cancer letter. According to the letter, the panel of experts was able to validate the results of the University researchers Nevins and Potti. It also reported that the IRB had consulted outside experts.

126. The names of the members of the group who validated the data were not released, the names of the experts were not released, the report was termed confidential and not made public, the text of the report was not released as it was termed confidential and not made public, and the raw data was not released.

127. In addition, Defendants Cuffe and Kornbluth wrote "Most importantly, an examination of the underlying scientific methodology that had been published by the Duke investigators, and used in these trials, was confirmed by the reviewers' own independent analysis using the respective datasets and prescribed methods of analysis. The reviewers concluded that the approaches used in the Duke clinical predictors are viable and likely to succeed,' and 'we believe the predictors are scientifically valid.'"

128. Citing the findings of the panel, Duke leadership including Duke University, DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson decided that the clinical trials were safe for the patients and indicated Duke was initiating processes to reopen enrollment in the involved trials.

129. The assertion that the panel of experts were able to validate the results of the University researchers Nevins and Potti was significant because it would constitute the first independent validation of the Duke genomic technology.

130. On May 14, 2010 a heavily redacted report of the Duke independent panel was released as a result of a FOIA request by The Cancer Letter to the National Cancer Institute in spite of Duke's belief that the report was confidential.

131. In contrast to Duke's public response, not only were the findings of Potti and Nevins irreproducible by others in the scientific community, but the external panel itself, even though expecting to receive all relevant information from Duke leadership and the Duke conglomerate, did not have sufficient information to reproduce the findings as disclosed in the actual report, saying in the report, "The one area that they [the Duke investigators] have not been fully responsive and really need to do so is in clearly explaining and laying our (sic) the specific statistical steps used in developing the predictors and the prospective sample assignments."

132. Instead of conducting a vigorous and comprehensive independent review of the flawed science and methodology, Nevins, Potti, Duke University and/or DUHS, Cuffe, Kornbluth and Harrelson, knowingly and willfully withheld relevant information from the "external panel," and chose instead to rely on the word of Potti and Nevins that the quality of the data was accurate and reliable. This was all done in an effort to protect the work of the Duke team of investigators including Nevins, Potti, and Methey-Prevot, from adverse judgment and professional condemnation, and also in an effort to protect the highly valuable proprietary interests of Duke and/or DUHS, its patents, corporations and venture capitalists.

133. Instead of conducting a rigorous and comprehensive independent review of the flawed science and methodology, Duke University and/or DUHS knowingly and willfully withheld relevant information from the "external panel" to ensure that the panel's findings would vindicate and substantiate the work of the Duke University and/or DUHS , including Nevins and Potti individually, despite notice that the same research may have been placing the safety of its own patients involved in the clinical trials in danger.

134. Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson were more committed to protecting the reputation, research, wealth and proprietary interests of Nevins, Potti, and Duke University and/or DUHS than in protecting the safety of the patients involved in the clinical trials.

135. Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson were more committed to protecting the reputation of Nevins, who they deemed to be an esteemed researcher serving Duke since 1987, and the face of Duke University and/or DUHS, than protecting the safety of the patient involved in the clinical trials.

136. Potti and Nevins individually were more committed to protecting their reputation, wealth and individual proprietary interest than protecting the safety of the patient involved in the clinical trials.

137. Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson had independent, non-delegable duties to act properly, with fairness and within the protocols of the Belmont Report as adopted by the U.S. Government into federal law pursuant to 45 C.F.R. Part 46, including the adoption by the U.S. Department of Defense.

138. In their failure to report all of the relevant information or to recommend or demand that all relevant information published by Baggerly and Coombes be submitted to the "external panel," and to the remaining members of the IRB, Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson each effectively invalidated the report of the external panel and handicapped the IRB.

139. By withholding relevant data from the" external panel" and the IRB, Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson each invalidated the conclusions made by the IRB.

140. In January 2010, Duke University and/or DUHS restarted the trials when they knew or should have known that the report issued by the independent reviewers was based on inaccurate data, misinformation, and fraud, misleading statements, misleading interpretations known by Duke University and/or DUHS to be misleading and false, all for the purpose of protecting the reputation, research, wealth and proprietary interests of Duke University and/or DUHS rather than protecting the safety of the patients involved in the clinical trials.

141. The entire response by Duke University and/or DUHS to the accusation of invalid and fraudulent science was deceptive, misleading, and fraudulent conduct designed to protect its reputation and proprietary interests in the furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large, rather than protecting the safety of the patients involved in the clinical trials.

142. Throughout 2009, Baggerly and Coombes issued warnings to Nevins, Potti and to Duke University and/or DUHS both directly and in publications that the clinical trials being conducted were based on questionable scientific research. These warnings put, or should have put, Nevins, Potti, Duke University and/or DUHS on notice that the trials could be putting patients at risk by exposing them to potentially ineffective or dangerous treatments.

143. Baggerly and Coombes pointed out the many notable holes in the report of the "external panel" and the glaringly poor oversight committed by defendants Cuffe and Kornbluth. The MD Anderson researchers again placed the Duke Defendants on notice that there was insufficient justification to restart the clinical trials.

144. Throughout 2010, Baggerly and Coombes issued warnings to Nevins, Potti and to Duke University and/or DUHS both personally and in publications that the clinical trials being conducted were based on questionable scientific research which put, or should have put Nevins, Potti and Duke University and/or DUHS on notice that the trials could be putting patients at risk by exposing them to potentially ineffective or dangerous treatments.

145. In July of 2010, "The Cancer Letter" broke the news that Potti was not, in fact, a Rhodes Scholar as he had previously claimed in various government and private foundation grants.

146. Upon learning of Potti's deceptive and fraudulent claims, the ACS stopped all funding toward the clinical trials at issues and demanded an explanation from Duke in July of 2010.

147. On July 19, 2010, a group of experienced biostatisticians and bioinformaticians wrote to Harold Varmus, the new head of the NCI, to ask that the Duke University and/or DUHS clinical cancer trials be suspended until the science was shown to be supported by the data.

Duke Defendants Suspend and Eventually Terminate the Valuable Clinical Trials as a Result of Public Revelations Surrounding Potti's Fraudulent Credentials

148. In the wake of the exposé surrounding Potti's fraudulent credentials, in July of 2010, Duke University and/or DUHS re-suspended the clinical trials at issue.

149. Finally, on November 29, 2010, all the clinical trials at issues were terminated. This represented the first time since the trial began that the Duke Defendants made the decision to actually terminate any of the three clinical trials at issue.

150. Baggerly and Coombes had been continually raising concerns since 2006 regarding errors and problems in Potti's work; however, the defendants chose to ignore this repeated notice and continue the clinical trials and risk the safety of the patients.

151. In publishing their findings, Baggerly and Coombes publicly made the Duke cancer team, Nevins, Potti, Duke University and/or DUHS, and all Defendants aware of errors and serious problems with the Duke cancer research and the potential for harm to the participants in the clinical trials at issue.

152. In order to create clinical trials, Duke University and/or DUHS, with the cooperation of Potti, Nevins and William Barry, Ph.D., had to create clinical trial protocols to present to the U.S. government, the NCI and to Duke's own IRB for review.

153. At the time that these protocols were created, Nevins, Potti and/or Barry knew or should have known that false and improper information had been included in the research upon which the clinical trial protocols were based.

154. The creation and implementation of clinical trials is an additional source of revenue for a facility such as Duke University.

155. Duke University and/or DUHS were motivated, in part, by this source of additional revenue in their creation of the clinical trials.

156. The individual Duke cancer researchers, including Nevins and Potti, were motivated, in part, by this source of additional revenue in their creation of the clinical trials.

157. The members of CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc. were motivated, in part, by this source of additional revenue in their creation of the clinical trials.

158. At the time that the clinical protocols were submitted to the IRB and to the U.S. government, neither Potti, Nevins nor anyone else at Duke University and/or DUHS informed either the IRB, the U.S. Government or any other entity that false and improper information had been included in the research upon which the clinical trial protocols were based, or even that questions had been raised about the research on multiple occasions

159. In preparing to conduct the above-mentioned clinical trials, Duke University and/or DUHS actively sought sponsors and grants.

160. In applying for sponsors and grants to outside organizations, Potti, as a member, employee and agent of Duke University and/or DUHS , and as a mentee and/or agent of Defendant Nevins, submitted applications and documents to the U.S. Government, its entities and to third party organizations. In Potti's applications and documents, he knowingly, willfully, falsely and fraudulently included incorrect and false information about his background and curriculum vitae in order to obtain money in the form of grants and sponsorships for himself and

for Duke University and/or DUHS. Each time that Potti submitted this false and fraudulent information, he committed fraud.

161. Each time that Potti submitted this false and fraudulent information, he acted as an employee, agent or servant of Duke University and/or DUHS acting within the course and scope of his employment.

162. Each time that Potti submitted this false and fraudulent information, neither Duke University nor DUHS corrected or informed the recipient that the information put forward by Potti was false, fraudulent and should not be relied upon.

163. At the time that Potti submitted the false and fraudulent information to entities outside of Duke University and/or DUHS, the defendants had the capacity and ability to check and confirm or disaffirm the truth of the credentials submitted by Potti.

164. Each time that Potti submitted this false and fraudulent information, Nevins, Dr. Cuffe, Dr. Kornbluth and Duke University and/or DUHS knew or should have known that that the information put forward by Potti was false, fraudulent and should not be relied upon.

165. At no point prior to July 2010 did Nevins, as the mentor and the direct supervisor of Potti, the director who hired Potti, or any of the Defendants including Duke University and/or DUHS verify the credentials and information submitted by Potti to Duke, the U.S. Government, its entities and to third parties in the form of sponsor and grant applications.

166. At the time that the clinical trials were conducted by Duke Drs. Marcom, Vlahovic, Garst and Ready, the flawed scientific research published in the NEJM and "Nature Medicine" articles, as well as the issues raised by Baggerly and Coombes, were available to the doctors. Each doctor had an individual, non-delegable duty to verify that the scientific research upon which the clinical trials were based was valid and not falsified.

167. Drs. Marcom, Vlahovic, Garst and Ready each had an individual, non-delegable duty to confirm that there were no major problems or issues with the clinical trials after Baggerly and Coombes published data questioning the very basis of the scientific research upon which the clinical trials were based.

168. As physicians working to provide care to cancer patients, the physicians had a duty to ensure that they did not put the cancer patients at risk of dangerous clinical trials that were only experimentation.

169. Numerous patients with early stage breast cancer were enrolled by Duke University and/or DUHS in the Breast Cancer Trial.

170. Numerous patients with stage IIIB/IV Non Small Cell Lung Cancer (NSCLC) were enrolled by Duke University and/or DUHS in Lung Cancer Trial 1.

171. Numerous patients with early stage Non Small Cell Lung Cancer (NSCLC) were enrolled by Duke University and/or DUHS in Lung Cancer Trial 2.

172. Duke University and/or DUHS in the form of Duke University Medical Center was a "responsible party" for Lung Cancer Trial 2 and the Breast Cancer Trial.

173. Duke University and/or DUHS in the form of Duke Comprehensive Medical Center was a "responsible party" for Lung Cancer Trial.

174. Duke University was a "sponsor and collaborator" of Lung Cancer Trials 1 and 2 and the Breast Cancer Trial.

175. Following each of the e-mails of concern and warning and the numerous publications of Baggerly and Coombes' articles setting out the concerns that the science was false, unreliable and bad, each of the Defendants were put on notice that there was a problem or potential problem with one or all of the clinical trials.

176. Following each of the e-mails of concern and warning and the numerous publications of Baggerly and Coombes' articles setting out the concerns that the science was false, unreliable and bad, each of the Defendants owed an individual, non-delegable duty to ensure that the participants in the clinical trials were not subject to experimentation based upon incorrect, false and or fraudulent clinical research.

177. The claims of Baggerly and Coombes were valid, and had foundation in facts that were equally available to the Defendants. In denying the same, Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson, publicized false and misleading statements to the public, to the Plaintiffs and to other participants in the clinical trials.

178. All of the information published and publicized by Baggerly and Coombes was made available to each of the Defendants. Each of the Defendants had an independent, non-delegable duty to verify and act upon that information.

179. Regardless of the obvious problems in the clinical trials and issue and the public outcry among the scientific and medical community, Duke leadership and Duke University

and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson did not terminate the clinical trials at issue until November of 2010.

Duke's Institution-Wide Decision to Cloud and Deny the Truth in the Wake of the Publicized Scandal

180. In response to the revelations about Potti and his credentials and faulty science, Duke leadership and Duke University and/or DUHS, Nevins, Potti, Cuffe, Kornbluth and Harrelson, in furtherance of their conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large created an atmosphere of distrust, retribution and intimidation.

181. Administration officials at Duke University and/or DUHS threatened staff with retribution, including legal action, should they speak with any outsiders and rather than ask anyone who had knowledge or suspicions about Potti's work or background to come forward, warned people not to even Google the name Anil Potti, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large.

182. Instead of interviewing in a welcoming and encouraging atmosphere anyone who had worked in the Nevins and Potti labs to figure out who suspected what about bad science and bad credentials and which deans they told, the administration and leadership of Duke University and/or DUHS stonewalled and explicitly warned staff and researchers not to discuss, investigate, explore or in any way deal with the Potti matter, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large.

183. Duke University and/or DUHS has to date neither adequately or fully informed all persons who participated or received any invasive procedure such as biopsies, other surgical procedures, or other tests used to qualify them as participants, or who received chemotherapy and/or radiation or any other treatment or regimen, or were in any way a part of or a participant in the Clinical Trials, of the fact that the consent obtained from them was invalid and false, and that they have been harmed by said participation, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large.

184. Duke University and/or DUHS did not notify the participants in the clinical trials at issue of a problem or potential problem with the trials until sometime in December 2010.

185. On various dates from December 2010 to February 2011, more than 6 months after the clinical trials were re- suspended because of the Potti scandal, Duke University and/or DUHS misrepresented and minimized the extent and severity of the experimentation on human subjects based on faulty science, and sought to suppress information the public and the plaintiffs had a right to know by sending letters to the plaintiffs, and others similarly situated, which minimized and misstated the extent of and severity of the problem and the potential risks to the plaintiffs in violation of its fiduciary duties to the Plaintiffs.

186. The form letter to those patients was misleading and deceptive in that the letters:

a. did not mention Potti and his fraudulent and false representations to the scientific world,
b. did not offer any explanation of when Duke University and/or DUHS had knowledge of the invalid science,
c. did not explain Duke's failure to terminate the clinical trial when they knew of the faulty science
d. did not tell of Duke's withholding of information to the panel that determined the clinical trials were safe,
e. did not give an explanation of the extent of the fraudulent and invalid science nor the extent of the retraction of the scientific data
f. did not offer any reasonable explanation or description of the problem
g. did not identify the nature of the harm or potential harm the patient may have suffered as a result of receiving chemotherapy that was not suitable to their type of cancer, and/or
h. did not offer advice as to what symptoms may have occurred or may occur in the future as a result of exposure to chemotherapy.

187. Potti was exposed for his false and fraudulent information contained in his applications and CV on June 16, 2010, yet he remained on the payroll of Duke University and/or DUHS with access to his laboratory, data, and documents until his resignation November 19, 2010.

188. The clinical trials at issues were the result of a sequence of systems failures undetected by and compounded by Nevins, Potti and other employees and agents of Duke University and/or DUHS, and/or CancerGuide Diagnostics, Inc.. Each of the Defendants had multiple opportunities to discover and correct the mistakes which led to the administration of dangerous and inappropriate chemotherapy to the Plaintiffs and the delay in properly treating his/her cancer, but the Defendants chose repeatedly to move forward with the clinical trials despite overt signs that they were based upon fraudulent and incorrect research.

189. The clinical trials at issue were not valid forms of medical research, but were instead inappropriate experiments, far short of the expected scientific standards, on people diagnosed with cancer. Although the Plaintiffs and other patients in the trials were told that they would receive the genomic test and its results would determine their treatment, that claim proved to be false, as the trials were based upon faulty genomic science and a failed chemotherapy sensitivity predictor model.

190. The clinical trials at issue were conducted on patients without their full informed knowledge or full consent to the fraud or of the fraudulent research and in violation of their trust in DUHS and Duke University's adherence to their fiduciary duties and their representations to them, as are set forth in more detail below.

191. All of the clinical trials at issue occurred after the Defendants knew or should have known that there was a serious problem with the Duke cancer researchers' data and research, and that the clinical trials were potentially dangerous. Defendants' efforts to resolve the problems prior to the initiation of the clinical trials at issue were wholly nonexistent. Defendants' efforts to solve the problems after the commencement of the clinical trials at issue were slow, unsubstantial and wholly failed to comply with the Defendants' existing policies and procedures, as well as their fiduciary duties to the patients in general and the Plaintiffs in particular.

192. Duke University and/or DUHS engaged in a course of deceptive conduct that was designed to minimize potential exposure to legal claims by patients who had been exposed to unnecessary chemotherapy medication to protect its reputation and its proprietary interests at the expense of plaintiffs patients' safety all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large.

193. Plaintiffs participated in various clinical trials as specified in Exhibits 1-8 attached hereto, each of said trials being administered and controlled by DUHS and/or Duke University, and their agents and employees

194. Had Plaintiffs been properly informed of the information and invalid science behind the clinical trials, Plaintiffs would have chosen not to participate in said trials.

III. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Protection of Human Subject Experimentation, Negligence Per Se

195. As part of Duke University and/or DUHS's duties to its' patients and the federal regulatory agencies involved during the Cancer Trials, Duke University and/or DUHS University and/or DUHS was obligated to comply with the applicable provisions of the Code of Federal Regulations, including but not limited to Title 45 part 46, entitled "Protection of Human Subjects" (hereinafter "45 CFR 46").

196. The intent of 45 CFR 46 was to ensure that the dignity of human subjects was not subordinate to the financial incentives of researchers and to provide protections for individuals asked to participate in a clinical trial or research.

197. The historical background of 45 CFR 46 included the standards developed by the Nuremberg Code of 1947 to protect the sanctity of human life by establishing safety standards for human subjects and to ensure that participation in a clinical trial, such as the Duke University and/or DUHS Cancer Trials, was the result of an informed consent. In 1979 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a report entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research, otherwise known as The Belmont Report. The United States, by adopting 45 CFR 46, recognized and affirmed the principles from the Belmont Report. The Belmont Report expressed three basic principles as particularly relevant to the ethics of research involving human subjects: Respect of persons, Beneficence and Justice.

198. The Belmont Report concluded that ethical research must respect individuals by ensuring that potential subjects of research enter into a research program voluntarily by making their own independent decisions after receiving all information necessary to make a considered judgment.

199. The Belmont Report also recognized that some individuals are entitled to additional protections. Patients that have been diagnosed with cancer are patients that are hopeful for help and therefore must be protected from the overzealous encouragement of health

care providers to participate in clinical trials that will expose the patient to unnecessary harm without benefit.

200. The ethical principle of Beneficence was defined by the Belmont report, in part, as follows:

> Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.
>
> The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others.

201. The Belmont Report principles, as codified in 45 CFR 46, defined an informed consent as one that provides all pertinent information, provides adequate opportunity to consider all options, is comprehended by the research subject, is accomplished to ensure voluntariness, and continues to provide information as the situation requires.

202. Federal and state law mandates that a participant enter into a valid informed consent.

203. The consent extracted from the participants by Duke was not voluntary, did not provide all pertinent information, did not provide adequate opportunity to consider all options, was not comprehensible, was untruthful, and fraudulently induced.

204. Duke University and/or DUHS told the plaintiffs that they had a new way of treating cancer that was better than anything that existed before. That statement was false.

205. Duke University and/or DUHS encouraged the plaintiffs to participate in the Clinical Trials.

206. Duke University and/or DUHS withheld all of the information regarding the substantial public and private criticisms made by other clinical researchers regarding the science upon which the Clinical Trials were based.

207. Duke University and/or DUHS withheld information from the plaintiffs regarding the fact that receiving chemotherapy at a particular stage of plaintiffs' cancer may not be

beneficial to him or her and that he/she could appropriately decide to forego such treatment and all of the pain, injury and suffering caused by the administration of chemotherapy.

208. Duke University and/or DUHS violated the principals of the Belmont Report by fraudulently obtaining the plaintiffs' consent to participate in the Clinical Trials.

209. Duke University and/or DUHS failed to comply with the requirements of 45 CFR 46-116, et.seq. due to the manner in which it persuaded plaintiffs to participate in the Clinical Trials.

210. The regulations contained in 45 CFR 46 are intended to protect the safety of research participants in Duke University and/or DUHS's Clinical Trials, such as plaintiffs.

211. Duke University and/or DUHS's failure to comply with the 45 CFR 46 is negligence per se.

212. In the conduct of its Cancer Trials, Duke University and/or DUHS was required, pursuant to 45 CFR 46-103(b) to certify to the applicable departments of the federal government to the following: (a) that the research upon which the Cancer Trials were based has been reviewed and approved by an Institutional Review Board (IRB), and (b) that the research will be subject to continuing review by the IRB.

213. Duke University and/or DUHS , through its IRB, failed to adequately review the research upon which the Clinical Trials at the time of initial approval and failed to continue and renew its review of the research as other renowned researchers called the Duke University and/or DUHS Clinical Trials into question.

214. Duke University and/or DUHS's failure to review the research initially and on a continuing basis after receiving actual notice that the research was based on false science and data is negligence per se.

215. As a direct and proximate result of the defendants' negligence per se based on violations of the regulations designed to prevent human experimentation, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages as referenced in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and caused the plaintiffs' intestates or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting from the defendants' negligence per se as outlined herein.

SECOND CLAIM FOR RELIEF
Corporate Negligence
(Duke University and/or DUHS)

216. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

217. Duke University and/or DUHS , through its Chief Executive Officers and Chief Operating Officers and other managerial, administrative and leadership employees at Duke, breached their managerial and administrative fiduciary duties to Plaintiffs and others similarly situated, when they:

a) failed to properly examine, check or confirm Potti's claimed credentials both at the time he was hired and during the process of applying for grants. Duke University and/or DUHS failed to determine that Potti was not a Rhodes Scholar, among other false accolades listed in his curriculum vitae, and failed to prevent him from lying to the U.S. Government and other non-governmental agencies, including the American Cancer Society and National Cancer Institute.

b) failed to properly exercise direct management control of their physicians and researchers on a full-time basis, including oversight to ensure that the policies and procedures as set out in the Belmont Report and adopted by various agencies, were consistently applied, followed and enforced;

c) failed to put patient's needs and medical care issues above financial incentives;

d) failed to develop, implement, and maintain effective adequate policies for creating a clinical trial that maintained the safety of participants;

e) failed to develop, implement, and maintain effective adequate policies for an IRB that would allow the IRB to put the needs of the participants in the clinical trials above those of Duke University and/or DUHS ;

f) failed to follow up in a timely or proper manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;

g) failed to timely or properly determine and then failed to timely inform all patients as expeditiously as practicable of any compromises in the clinical trials and any potential or actual risks to their health, including informing them of the questions and issues raised by the outside researchers and the formation of the "external panel" to review the clinical trials at issue, and, in particular, delayed disclosure of information to patients, or no

disclosure of the risks, after Duke University and/or DUHS halted the clinical trials;

h) failed to obtain necessary FDA approval of the clinical trials after the attempt to obtain pre-IDE approval;

i) failed to ensure that information submitted to the public in the form of Duke University and/or DUHS publications contained correct, valid information;

j) failed to perform computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues prior to the formation of the clinical trials at issue;

k) failed to provide necessary and complete information to the IRB and "external panel" to allow the highest level of review of the clinical trials;

l) failed to adequately protect and promote the rights and safety of patients in their clinical trials;

m) failed to adequately protect and promote the rights and safety of patients;

n) failed to timely terminate, not suspend, the clinical trials at issue once the errors and problems in the underlying research came to light;

o) failed to ensure that patients in certain clinical trials received appropriate, first line standard of care chemotherapy treatments for their cancer;

p) failed to ensure that patients with known cancer diagnoses were not receiving dangerous, incorrect medication in the form of wrong, incorrect chemotherapy treatment;

q) failed to appropriately implement a timely procedure for reporting the occurrence of any unusual incidents, analyzing such reports, and timely taking corrective actions, so that over three years passed before Duke University and/or DUHS took action to ensure that patients were not being used as "guinea pigs" in their experiments;

r) failed to properly monitor and oversee the compliance of all employees and agents with safety standards the hospitals were either legally required to abide by, or voluntarily agreed to abide by including applicable JCAHO requirements for accredited hospitals;

s) failed to properly monitor and oversee the compliance of all employees and agents with the federal standards adopted by the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), and the Common Rule as adopted by various governmental entities including the U.S. DoD;

t) failed to provide patient services in accordance with acceptable standards of practice applicable to professionals providing patients services and other staff providing support services in its hospitals;

u) failed, in response to the investigation about the faulty science and invalid clinical trials, to properly conduct a complete and open investigation and evaluation, and instead created an atmosphere of distrust, retribution and intimidation in furtherance of its conspiracy to obstruct justice and keep information from plaintiffs and the public at large;

w) misrepresented and minimized to the public and their patients the extent and severity of the experimentation based on faulty science;

x) suppressed information to the public and their patients to which the plaintiffs and the public had a right to know;

y) sent a misleading and deceptive letter to the plaintiffs minimizing and misstating the extent and severity of the problem with the faulty science and the potential risk to the plaintiffs;

z) engaged in a course of deceptive corporate conduct that was designed to minimize potential exposure to legal claims by patients who had been exposed to unnecessary chemotherapy medication to protect its reputation and its proprietary interests at the expense of plaintiff patients' safety, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large and in violation of its fiduciary duty; and

aa) committed other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

218. As a direct and proximate result of the defendants' corporate negligence as outlined herein, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence as outlined herein.

THIRD CLAIM FOR RELIEF
Ordinary Negligence
(Individual Employees of Duke University and/or DUHS)

219. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporates each by reference as if fully set forth herein.

220. Duke University and/or DUHS employees and agents failed to exercise ordinary care in the following occurrences:

a) when Dr. Cuffe, Dr. Kornbluth and Dr. Harrelson failed to provide full and complete information to the remaining IRB members and to the "external panel";

b) when Dr. Cuffe, Dr. Kornbluth and Dr. Harrelson allowed the clinical trials at issue to continue after they received a report from the "external panel" based upon insufficient and incomplete information submitted by same;

c) when Dr. Cuffe, Kornbluth and Dr. Harrelson violated the precepts of the IRB by not allowing the IRB to proceed independently with access to full and complete information from the MD Anderson researchers;

d) when Dr. Cuffe and Dr. Kornbluth published false and incomplete information regarding the clinical trials and the "external panel" report;

e) when Dr. Cuffe, Dr. Kornbluth and Dr. Harrelson violated state law, JCAHO requirements, and federal regulations from the U.S. Department of Health and Human Services, the DoD and the Common Law;

f) when Potti and Nevins failed in their responsibilities as researchers and in their publication and dissemination of false and incorrect information;

g) when defendants actively put patients in danger in clinical trials based upon falsified, incorrect research without fully informing the patients of same;

h) when defendants allowed patients under their care to continue to be subject to medical experimentation when they knew or should have known that the underlying research had been challenged as being invalid and false;

i) when defendants allowed patients under their care to become subject in the medical experiments without making a true determination of the underlying research at issue;

j) failed to have an adequate policy in place that provided for the safety of participants in clinical trials;

k) failed to have sufficient organizational oversight of clinical trials to provide minimal protections for participants of clinical trials from becoming mere participants in gross medical experiments;

l) failed to put patient's needs and medical care issues above financial incentives;

m) failed to follow up in a timely or proper manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;

n) failed to adequately protect and promote the rights and safety of patients;
o) failed to adequately protect and promote the rights and safety of patients in their clinical trials; and
p) committed other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

221. As a direct and proximate result of the negligence as described herein, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence as outlined herein.

FOURTH CLAIM FOR RELIEF
Breach of Fiduciary Duty
(Duke University and/or DUHS)

222. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

223. At all times material hereto, a special relationship existed between the Plaintiffs and Duke University and/or DUHS. This relationship was such that Plaintiffs placed a special confidence and trust in Duke University and/or DUHS , and Duke University and/or DUHS was a fiduciary of patients generally and of Plaintiffs in particular.

224. Duke University and/or DUHS breached their ethical, moral and "responsible party" duties, as well as their and administrative and fiduciary duties to Plaintiffs and others similarly situated, when they:

a) failed to properly examine Dr. Potti's credentials to determine that Potti was not a Rhodes Scholar, among other false accolades listed in his curriculum vitae, and to prevent him from lying to the U.S. government and other non-governmental agencies.
b) failed to exercise basic oversight to ensure that the principles, policies, and procedures as set out in the Belmont Report and adopted by various

agencies such as the NCI and U.S. DoD, were consistently applied, followed, and enforced in the clinical trials;

c) failed to put patient's needs and medical care issues above financial incentives;

d) failed to develop, implement, and maintain effective policies for creating a clinical trial that maintained the safety of participants;

e) failed to follow up in a timely or proper manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;

f) failed to ensure that Duke University and/or DUHS had obtained necessary FDA approval of the clinical trials;

g) failed to ensure that information submitted to the public regarding the clinical trials contained correct, valid information;

h) failed to perform computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues prior to the formation of the clinical trials;

i) failed to adequately protect and promote the rights and safety of patients in their clinical trials;

j) failed to adequately protect and promote the rights and safety of patients;

k) failed to timely terminate, not suspend, the clinical trials at issue once the gross errors and problems in the underlying research came to light;

l) failed to ensure that patients in the clinical trials received appropriate, standard of care chemotherapy treatments for their cancer;

m) failed to ensure that patients with known cancer diagnoses were not receiving dangerous, incorrect medications in the form of wrong chemotherapy treatment;

n) failed in response to the investigation about the faulty science and invalid clinical trials, to conduct a complete and open investigation and evaluation, and instead created an atmosphere of distrust, retribution and intimidation in furtherance of its conspiracy to obstruct justice and keep information from plaintiffs and the public at large;

o) intentionally misrepresented and minimized to the public and their patients the extent and severity of the experimentation based on faulty science;

p) intentionally suppressed information to the public and their patients that the plaintiffs and the public had a right to know;

q) intentionally sent a misleading and deceptive letter to the plaintiffs minimizing and misstating the extent and severity of the problem with the faulty science and the potential risk to the plaintiffs;

r) intentionally engaged in a course of deceptive corporate conduct that was designed to minimize potential exposure to legal claims by patients who had been exposed to unnecessary chemotherapy medication, to protect its reputation and its proprietary interests at the expense of plaintiffs patients' safety, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large and in violation of its fiduciary duty;

s) failed to adequately or fully inform all persons who participated or received any invasive procedure such as biopsies, other surgical procedures, or other test used to qualify them as participants, or who received chemotherapy and/or radiation or any other treatment or regimen or were in any way a part of or a participant in the Clinical Trials, of the fact that science and information underlying the clinical trials was faulty and fraudulent, and that the consent obtained from them was therefore invalid, and that they have been harmed by said participation, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large;

t) committed other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

225. As a direct and proximate result of Duke University and/or DUHS's negligence and breach of fiduciary duties, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

FIFTH CLAIM FOR RELIEF
Medical Negligence In The Alternative
(Duke University and/or Duke University Health System, Inc.)

226. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporates each by reference as if fully set forth herein.

227. Plaintiffs believe and allege that the acts of negligence which are complained of herein were acts that did not require medical expertise to perform within the standard of care envisioned by N.C. Gen. Stat.20-21.12 and NC Rule of Evidence 702(b) et seq., nor N.C. Rule of Civil Procedure 9(j); however, in light of the unsettled nature of this area of the law, and in an abundance of caution, Plaintiffs allege medical negligence as an alternative theory of liability, because some of what Plaintiffs consider to be ordinary negligence occurred during the provision of professional medical services which may be construed as professional negligence by the court. It is the position of the Plaintiffs that no reasonable person would in the exercise of ordinary, reasonable care commit the acts and/or negligently fail to commit the acts, which are complained of herein. With those caveats and explanations, Plaintiffs allege in the alternative the following medical negligence in this claim for relief.

228. Duke University and/or DUHS undertook to provide medical care to the Plaintiffs and others similarly situated.

229. A hospital-patient relationship existed between Duke University and/or DUHS and the Plaintiffs, and in rendering medical care to the plaintiffs, Duke University and/or DUHS failed to comply with the applicable standard of care.

230. At all times relevant to this complaint, Duke University and/or DUHS and its employees and agents failed to use reasonable care and diligence in the application of their knowledge and skill to the care of the Plaintiffs and others similarly situated.

231. At all times relevant to this complaint, Duke University and/or DUHS and its employees and agents failed to use their best judgment in the treatment and care of Plaintiffs and others similarly situated while they were patients and/or participating in Duke University and/or DUHS 's clinical cancer trial.

232. Duke University and/or DUHS and its employees and agents failed to provide treatment to Plaintiffs and others similarly situated which was in accordance with the standards of practice among members of the nursing, medical oncology, surgical, and other health care professions and other medical support professions with similar training and experience.

233. The Plaintiffs object to the requirements of Rule 9(j) of the North Carolina Rules of Civil Procedure on the basis that this Rule seems to require plaintiffs to prove their case before factual discovery is even begun, and objects to Rule 9(j), NC Rule of Evidence 702(b) et seq., and N.C. Gen. Stat. 90-21.12 as these rules and statutes deny medical malpractice plaintiffs

their rights of due process of law, of equal protection under the law, of the right to open courts, and of the right to a jury trial (in violation of the United States and North Carolina Constitutions) and, further, that Rule 9(j) is an unconstitutional violation of the following: (A) Amendment VII and Amendment XIV of the United States constitution; (B) Article I, Sections 18, 19 and 25 of the North Carolina Constitution. In addition, the Plaintiffs object to the requirements of N.C. R. Civ. Pro. 9(j) and N.C. R. Evid. 702(b) et. seq., as applied to the allegations contained herein of ordinary negligence by health care providers at Duke University and/or DUHS who failed to review the basic mathematical and statistical computations in the underlying research at issue to determine whether there were gross errors in the data which formed the basis of the clinical trials, which they contend do not involve medical negligence.

234. Without waiving the objections identified in the preceding paragraph, the Plaintiffs acknowledge that Duke University and/or DUHS may claim that some of the allegations against DUHS may involve medical care. Such medical care referred to in this complaint has been reviewed by persons who are reasonably expected to qualify or whom plaintiffs will seek to have qualified as experts under Rule 702 of the North Carolina Rules of Evidence and who are willing to testify that the medical care identified herein did not comply with the applicable standards of care.

235. Without waiving the objections identified in the preceding paragraphs, Duke University and/or DUHS , by and through its physicians, researchers, administrators, employees and/or agents, breached the applicable standards of care in the following ways:

a. made the decision to deliver chemotherapy treatment to the Plaintiffs in the setting of a clinical trial based upon flawed scientific research and a faulty chemotherapy sensitivity predictor model;
b. failed to provide the Plaintiffs with informed consent, as outlined herein, about their enrollment and continued participation in the clinical trials in the following ways:
c. failing to inform the Plaintiffs that the data upon which the clinical trial at issue was based was filled with errors;
d. failing to inform the Plaintiffs that Potti actively lied regarding his credentials and accolades in sponsorship applications;
e. failing to inform the Plaintiffs that they may not actually receive the "best" chemotherapy treatment as shown by the LSM model;
f. misrepresenting the fact that the Plaintiffs may not receive the standard chemotherapy for his/her cancer;

g. misrepresented to the Plaintiffs that the proposed regimen had an 80% effectiveness rate
h. failed to properly and fully advise Plaintiffs, without the bias of the alleged success of the clinical trial regimens, that one option was to take no chemotherapy, and that the benefit of the proposed regimen may not outweigh the touted benefit
i. failing to adequately disclose the extent to which the Defendants had conflicts of interest;
j. failing to adequately disclose the financial interest that Duke University and/or DUHS, Drs. Potti, Nevins, other physicians and administrative and managerial officials and officers had in relation to the study;
k. failing to adequately disclose the inherent conflicts of interest among the members of the Duke IRB and other investigational bodies created to monitor the data and safety surrounding the clinical trials;
l. failing to inform the Plaintiffs that outside researchers had raised serious issues and concerns regarding the cancer research and issue and the safety of the clinical trials;
m. failing to inform the Plaintiffs that the "external panel" and the IRB's findings and "validation" had been improperly based upon a lack of information provided to same by Drs. Cuffe, Kornbluth and Harrelson;
n. allowing the Plaintiffs to participate in the clinical trial after the trial should have been terminated;
o. failed to properly examine, check or confirm Potti's claimed credentials both at the time he was hired and during the process of applying for grants. Duke University and/or DUHS failed to determine that Potti was not a Rhodes Scholar, among other false accolades listed in his curriculum vitae, and failed to prevent him from lying to the U.S. Government and other non-governmental agencies, including the ACS and NCI.
p. failed to properly exercise direct management control of their physicians and researchers on a full-time basis, including oversight to ensure that the policies and procedures as set out in the Belmont Report and adopted by various agencies, were consistently applied, followed and enforced;
q. failed to put patient's needs and medical care issues above financial incentives;
r. failed to develop, implement, and maintain effective adequate policies for creating a clinical trial that maintained the safety of participants;
s. failed to develop, implement, and maintain effective adequate policies for an IRB that would allow the IRB to put the needs of the participants in the clinical trials above those of Duke University and/or DUHS;

t. failed to follow up in a timely or proper manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;

u. failed to timely or properly determine and then failed to timely inform all patients as expeditiously as practicable of any compromises in the clinical trials and any potential or actual risks to their health, including informing them of the questions and issues raised by the outside researchers and the formation of the "external panel" to review the clinical trials at issue, and, in particular, delayed disclosure of information or risks to patients, after Duke University and/or DUHS halted the clinical trials;

v. failed to obtain necessary FDA approval of the clinical trials after the attempt to obtain pre-IDE approval;

w. failed to ensure that information submitted to the public in the form of Duke University and/or DUHS publications contained correct, valid information;

x. failed to perform computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues prior to the formation of the clinical trials at issue;

y. failed to provide necessary and complete information to the IRB and "external panel" to allow the highest level of review of the clinical trials;

z. failed to adequately protect and promote the rights and safety of patients in their clinical trials;

aa. failed to adequately protect and promote the rights and safety of patients;

bb. failed to timely terminate, not suspend, the clinical trials at issues once the errors and problems in the underlying research came to light;

cc. failed to ensure that patients in the clinical trials received appropriate, standard of care chemotherapy treatments for their cancer;

dd. failed to ensure that patients with known cancer diagnoses were not receiving dangerous, incorrect medication in the form of wrong, incorrect chemotherapy treatment;

ee. failed to appropriately implement a timely procedure for reporting the occurrence of any unusual incidents, analyzing such reports, and timely taking corrective actions, so that over three years passed before Duke University and/or DUHS took action to ensure that patients were not being used as "guinea pigs" in experiments;

ff. failed to properly monitor and oversee the compliance of all employees and agents with safety standards the hospitals were either legally required to abide by, or voluntarily agreed to abide by, including applicable JCAHO requirements for accredited hospitals;

gg. failed to properly monitor and oversee the compliance of all employees and agents with the federal standards adopted by the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), and the Common Rule as adopted by various governmental entities including the U.S. DoD; and,

hh. failed to provide patient services in accordance with acceptable standards of practice applicable to professionals providing patients services and other staff providing support services in its hospitals;

ii. failed in response to the investigation about the faulty science and invalid clinical trials, to properly conduct a complete and open investigation and evaluation and instead created an atmosphere of distrust, retribution and intimidation in furtherance of its conspiracy to obstruct justice and keep information from plaintiffs and the public at large;

jj. misrepresented and minimized to the public and their patients the extent and severity of the experimentation based on faulty science;

kk. suppressed information to the public and their patients which the plaintiffs and the public had a right to know;

ll. sent a misleading and deceptive letter to the plaintiffs minimizing and misstating the extent and severity of the problem with the faulty science and the potential risk to the plaintiffs;

mm. engaged in a course of deceptive corporate conduct that was designed to minimize potential exposure to legal claims by patients who had been exposed to unnecessary chemotherapy medication, to protect its reputation and its proprietary interests at the expense of plaintiffs patients' safety, all in furtherance of its conspiracy to obstruct justice and keep information from potential plaintiffs and the public at large and in violation of its fiduciary duty; and

nn. committed other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

236. As a direct and proximate result of Duke University and/or DUHS's negligence, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

SIXTH CLAIM FOR RELIEF
Ordinary Negligence
(Anil Potti, MD)

237. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

238. Anil Potti, MD, failed to exercise ordinary care in the following occurrences:

a) committed fraud in statement of his credentials;
b) committed fraud in applications for grants and monetary assistance;
c) committed fraud in his research;
d) allowed or used fraudulent and invalid research to formulate clinical trials that put patients at risk for serious harm and death;
e) began and continued a conspiracy to falsify and commit fraud in order to cover up his own actions and those of other actors at Duke University and/or DUHS in order to protect his reputation and proprietary interests;
f) failed to put patient's needs and medical care issues above financial incentives;
g) failed to follow up in a timely manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;
h) failed to exercise direct management control of staff and researchers on a full-time basis, including oversight to ensure that the principles, policies, and procedures as set out in the Belmont Report and adopted by various agencies, were consistently applied, followed, and enforced;
i) failed to perform computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues prior to the formation of the clinical trials at issue;
j) failed to provide full and complete information to the IRB and "external panel" to allow the highest level of review of the clinical trials;
k) failed to protect and promote the rights and safety of patients;
l) failed to protect and promote the rights and safety of patients in their clinical trials;
m) put patients in danger in clinical trials based upon falsified, incorrect research without fully informing the patients of same;
n) put patients in clinical trials without first informing them of the true nature of his academic and professional credentials and/or the fraudulent applications he had made to Duke, the U.S. government and other entities containing falsely reported credentials;

o) allowed patients under his care to continue to be subject to medical experimentation when he knew or should have known that the underlying research had been challenged as being invalid and false;
p) allowed patients under his care to become subjects in the medical experiments without making a true determination of the underlying research at issue;
q) accepted payment from Duke University and/or DUHS, and the U.S. DoD to perform clinical trials without first taking the initial steps of ensuring that the underlying research was sound, or without informing them of his fraudulently reported credentials;
r) actively placed his patients in danger of serious harm and death.
s) by other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

239. As a direct and proximate result of Anil Potti's negligence, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

SEVENTH CLAIM FOR RELIEF
Ordinary Negligence
(Joseph R. Nevins, PhD)

240. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

241. Joseph R. Nevins, PhD, failed to exercise ordinary care in the following occurrences:

a) committed fraud in his research;
b) allowed or used fraudulent and invalid research to formulate clinical trials that put patients at risk for serious harm and death;

c) began and continued a conspiracy to falsify and commit fraud in order to cover up his own actions and those of other actors at Duke University and/or DUHS in order to protect his reputation and proprietary interests;
d) failed to properly examine or confirm Potti's credentials fully both at the time he was hired, during the process of applying for grants, and for a period of time during which patients were being subject to clinical trial testing;
e) failed to put patient's needs and medical care issues above financial incentives;
f) failed to follow up in a timely manner on questions and issues raised by outside clinical researchers regarding substantial errors in research which those outside researchers predicted could endanger clinical trial participants;
g) failed to exercise direct management control of physicians, staff and researchers on a full-time basis, including oversight to ensure that the policies and procedures as set out in the Belmont Report and adopted by various agencies, were consistently applied and followed, and they were enforced;
h) failed to obtain necessary FDA approval of the clinical trials after the attempt to obtain pre-IDE approval;
i) failed to perform computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues prior to the formation of the clinical trials at issue;
j) failed to provide full and complete information to the IRB and "external panel" to allow the highest level of review of the clinical trials;
k) failed to protect and promote the rights and safety of patients;
l) failed to protect and promote the rights and safety of patients in their clinical trials;
m) by other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

242. As a direct and proximate result of Joseph R. Nevins's negligence, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of

$10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

EIGHTH CLAIM FOR RELIEF
Medical Negligence In The Alternative
(Anil Potti)

243. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporates each by reference as if fully set forth herein.

244. Plaintiffs believe and allege that the acts of negligence which are complained of herein were not acts that required medical expertise to perform within the standard of care envisioned by N.C. Gen. Stat.20-21.12 and NC Rule of Evidence 702(b) et seq., nor N.C. Rule of Civil Procedure 9(j); however, in light of the unsettled nature of this area of the law, and in an abundance of caution, Plaintiffs allege medical negligence as an alternative theory of liability, because some of what Plaintiffs consider to be ordinary negligence occurred during the provision of professional medical services which may be construed as professional negligence by the court. It is the position of the Plaintiffs that no reasonable person would in the exercise of ordinary, reasonable care commit the acts and/or negligently fail to commit the acts, which are complained of herein. With those caveats and explanations, Plaintiffs allege in the alternative the following medical negligence in this claim for relief.

245. Dr. Anil Potti undertook to provide medical care to the Plaintiffs and others similarly situated.

246. A physician-patient relationship existed between Potti and the Plaintiffs and in rendering medical care to the Plaintiffs, Potti failed to comply with the applicable standard of care.

247. At all times relevant to this complaint, Potti failed to use reasonable care and diligence in the application of his knowledge and skill to the care of the Plaintiffs and others similarly situated.

248. At all times relevant to this complaint, Potti failed to use his best judgment in the treatment and care of Plaintiffs and others similarly situated while they were patients of Potti.

249. Potti failed to provide Plaintiffs and others similarly situated treatment which was in accordance with the standards of practice among members of the medical profession with similar training and experience:

250. The Plaintiffs object to the requirements of Rule 9(j) of the North Carolina Rules of Civil Procedure on the basis that this Rule seems to require plaintiffs to prove their case before factual discovery is even begun, and objects to Rule 9(j), NC Rule of Evidence 702(b) et seq., and N.C. Gen. Stat. 90-21.12 as these rules and statutes deny medical malpractice plaintiffs their rights of due process of law, of equal protection under the law, of the right to open courts, and of the right to a jury trial (in violation of the United States and North Carolina Constitutions) and, further, that Rule 9(j) is an unconstitutional violation of the following: (A) Amendment VII and Amendment XIV of the United States constitution; (B) Article I, Sections 18, 19 and 25 of the North Carolina Constitution. In addition, the Plaintiffs object to the requirements of N.C. R. Civ. Pro. 9(j) and N.C. R. Evid. 702(b) et. seq., as applied to the allegations contained herein of ordinary negligence by defendants who failed to review the basic mathematical and statistical computations in the underlying research at issue to determine whether there were gross errors in the data which formed the basis of the clinical trials, which they contend do not involve medical negligence.

251. Without waiving the objections identified in the preceding paragraph, the Plaintiffs acknowledge that Potti may claim that some of the allegations against him may involve medical care. Such medical care referred to in this complaint has been reviewed by persons who are reasonably expected to qualify or whom plaintiffs will seek to have qualified as experts under Rule 702 of the North Carolina Rules of Evidence and who are willing to testify that the medical care identified herein did not comply with the applicable standards of care.

252. Without waiving the objections identified in the preceding paragraphs, Defendant Potti breached the applicable standards of care in the following ways:

a) made the decision to deliver chemotherapy treatment to plaintiffs in the setting of a clinical trial based upon flawed scientific research and a faulty chemotherapy sensitivity predictor model;
b) delivered a chemotherapy regimen of treatment to plaintiffs that was below the standard of care for the treatment of plaintiffs' cancer;
c) failed to provide plaintiffs with informed consent about their enrollment and continued participation in the clinical trials in the following ways;

d) failed to inform the Plaintiffs that the data upon which the clinical trial at issue was based was filled with errors;
e) failed to inform the Plaintiffs that Potti actively lied regarding his credentials and accolades in sponsorship applications;
f) failed to inform the Plaintiffs that he/she may not actually receive the "best" chemotherapy treatment as shown by the LSM model;
g) misrepresented the fact that the Plaintiffs may not receive the standard chemotherapy for his/her cancer;
h) misrepresented to the Plaintiffs that the proposed regimen had an 80% effectiveness rate;
i) failed to properly and fully advise Plaintiffs, without the bias of the alleged success of the clinical trial regimens, that one option was to take no chemotherapy, and that the benefit of the proposed regimen may not outweigh the touted benefit;
j) failed to adequately disclose the extent to which the Defendants had conflicts of interest;
k) failed to adequately disclose the financial interest that Duke University and/or DUHS , Drs. Potti, Nevins, other physicians and administrative and managerial officials and officers had in relation to the study;
l) failed to adequately disclose the inherent conflicts of interest among the members of the Duke IRB and other investigational bodies created to monitor the data and safety surrounding the clinical trials;
m) failed to inform the Plaintiffs that outside researchers had raised serious issues and concerns regarding the cancer research and issue and the safety of the clinical trials;
n) failed to inform the Plaintiffs that the "external panel" and the IRB's findings and "validation" had been improperly based upon a lack of information provided to same by Drs. Cuffe, Kornbluth and Harrelson;
o) allowed the Plaintiffs to participate in the clinical trial after the trial should have been terminated;
p) by other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

253. As a direct and proximate result of Dr. Potti's negligence, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension

and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

NINTH CLAIM FOR RELIEF
Breach Of Fiduciary Duty And Constructive Fraud
(Duke University and/or Duke University Health System, Inc.)

254. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

255. At all times material hereto, a hospital-patient relationship existed between the Plaintiffs and Duke University and/or DUHS . This relationship was such that Plaintiffs placed a special confidence and trust in Duke University and/or DUHS. Duke University and/or DUHS was a fiduciary of its patients generally and of Plaintiffs in particular.

256. By virtue of this relationship, Duke University and/or DUHS was and continues to be required to act in good faith and with due regard for plaintiffs and other patients' interests but failed and continues to fail to do so, by placing its own interest in protecting itself from liability and public scrutiny ahead of the interests of the plaintiffs and other patients, as is alleged in detail in the preceding and subsequent paragraphs.

257. DUHS along with the other Defendants was in sole possession of information regarding the research produced and provided by the Duke cancer researchers, which were the basis of the clinical trials, during which Plaintiffs were exposed to incorrect and improper chemotherapy, and Duke University and/or DUHS maintained control regarding the disclosure of this information.

258. Duke University and/or DUHS failed to make a full, open disclosure of material facts, and failed to deal with Plaintiffs and others similarly situated fairly and honestly.

259. Duke University and/or DUHS 's failure to act openly, fairly and honestly with respect to the Plaintiffs constitutes a breach of Duke University and/or DUHS 's fiduciary relationship and constructive fraud.

260. As a direct and proximate result of Duke University and/or DUHS 's breach of its fiduciary relationship and constructive fraud, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused

plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

TENTH CLAIM FOR RELIEF
Breach of Fiduciary Duty And Constructive Fraud
(Individual Defendants)

261. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

262. At all times material hereto, a special confidential relationship existed between the Plaintiffs and Potti Nevins, Cuffe, Kornbluth and/or Harrelson. This relationship was such that Plaintiffs placed a special confidence and trust in the above-mentioned physicians and individuals. The above-mentioned physicians were a fiduciary of their patients generally and of Plaintiffs in particular.

263. By virtue of this relationship, the above-mentioned physicians were and continue to be required to act in good faith and with due regard for Plaintiffs and other patients' interests but failed and continued to fail to do so, placing their own interests in providing for their own financial interests in protecting themselves from liability and public scrutiny ahead of the interests of the Plaintiffs and other patients, as is alleged in detail in the preceding and subsequent paragraphs.

264. The above-mentioned physicians along with the other Defendants were in possession of information regarding the research produced and provided by the Duke cancer researchers which were the basis of the clinical trials, during which Plaintiffs were exposed to incorrect and improper chemotherapy, and the above-mentioned physicians maintained control regarding the disclosure of this information.

265. The above-mentioned physicians failed to make a full, open disclosure of material facts, and failed to deal with Plaintiffs and others similarly situated fairly and honestly.

266. The above-mentioned physicians' failure to act openly, fairly and honestly with respect to the Plaintiffs constituted a breach of their fiduciary relationship and constructive fraud.

267. As a direct and proximate result of the above-mentioned physicians' breach of their fiduciary relationship and constructive fraud, the plaintiff's intestate or plaintiff individually

suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from the defendants' negligence per se as outlined herein.

ELEVENTH CLAIM FOR RELIEF
Misrepresentation/Unjust Enrichment
(CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc.)

268. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

269. In 2006, CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc. was founded with the motive of capitalizing on any financial gains realized by the Duke cancer researchers in the form of patents, clinical trials and other income generating activities.

270. The founders include Potti, who became a Director and Secretary; Nevins, who became the Treasurer and a Director; Mr. Ginsburg, who became a Director and Vice President; and Judd Staples, who became a Director and the President of the company.

271. Based upon their work on the Duke cancer research at issue at Duke University, Potti and Nevins applied for numerous patents, which involved the use of the Duke cancer research and specifically, the "LSM" model that was later supposed to be the basis of the clinical trials.

272. From 2006 until 2010, CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc. made profit based upon the work of its Directors and members with the Duke cancer research and clinical trials at issue.

273. During that time, neither CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc. nor any of its individual members, officers or directors acknowledged that the research at issue contained false and fraudulent information, errors and problems or that Potti lacked the credentials that he publicly claimed to have when they knew or should have known the same to be true.

274. As a direct result of their misrepresentation, CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc. reaped unjust profits from the Plaintiffs by misrepresenting information to the public.

275. As a direct and proximate result of the misrepresentation and unjust enrichment of CancerGuide Diagnostics, Inc. f/k/a Oncogenomics, Inc., the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from defendants' misrepresentation and unjust enrichment as outlined herein.

TWELTH CLAIM FOR RELIEF
Misrepresentation/Unjust Enrichment
(Duke University and/or DUHS)

276. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

277. In 2006, Duke University and/or DUHS began discussions with the Duke cancer researchers, specifically Potti, Nevins, Mr. Ginsburg and Mr. Barry, regarding their research and patents and any financial interests that might arise as a result of their research.

278. During this time, Duke University and/or DUHS either held no meetings or held an insufficient number of meetings to determine what, if any, conflicts of interest would arise if an agreement was entered into between Duke University and/or DUHS, U.S. Governmental and non-governmental sponsors and the Duke cancer researchers.

279. The financial gain of Duke University and/or DUHS in the form of making money by using cancer patients in experiments was an open and obvious conflict of interest for Duke University and/or DUHS. Duke University and/or DUHS were aware that the clinical trials would provide money to themselves and would directly benefit Potti, Nevins, and all of the Duke cancer researchers and physicians who were paid by the sponsors, including Drs. Potti, Marcom, Garst and Ready.

280. Furthermore, individual defendants who worked for Duke University and/or DUHS , including Potti and Nevins, knew that false, fraudulent, and incorrect data was the basis of the Duke cancer research and clinical trials at issue. And, making money from the clinical trials would be unjust enrichment to Duke University and/or DUHS based upon these misrepresentations.

281. Despite such express knowledge of the conflict of interest and the potential for unjust enrichment, Duke University and/or DUHS misrepresented information and formed agreements with outside sponsors for financial gain, and continued those relationships and agreements in the face of mounting evidence that the science was faulty and the clinical trials thus unjustified.

282. As a direct and proximate result of the misrepresentation and unjust enrichment of Duke University and/or DUHS , the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from defendants' misrepresentation and unjust enrichment as outlined herein..

THIRTEENTH CLAIM FOR RELIEF
Misrepresentation/Unjust Enrichment
(Individual Defendants)

283. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

284. Potti and Nevins published incorrect, error filled data in both the NEJM and in the journal "Nature Medicine" in 2006 with the motive of capitalizing on any financial gains realized by the Duke cancer researchers in the form of patents, clinical trials and other income generating activities.

285. Based upon their work on the Duke cancer research at issue at Duke University and/or DUHS, Potti and Nevins applied for numerous patents, which involved the use of the Duke cancer research and specifically, the "LSM" model that was later supposed to be the basis of the clinical trials.

286. From 2006 until 2010, neither Potti nor Nevins acknowledged that the research at issue had false and fraudulent information, errors and problems or that Potti lacked the credentials that he publicly claimed to have when they knew or should have known the same to be true.

287. As a direct result of their misrepresentation, Potti and Nevins reaped unjust profits from the Plaintiffs by lying, falsifying and misrepresenting information to the public.

288. As a direct and proximate result of the misrepresentation and unjust enrichment of Potti and Nevins, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from defendants' misrepresentation and unjust enrichment as outlined herein.

FOURTEENTH CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices
(Duke University and/or Duke University Health System, Inc.)

289. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

290. The alleged actions of Duke University and/or DUHS were unfair, deceptive, offensive to established public policy, and were immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers, including the Plaintiffs.

291. The alleged actions of Duke University and/or DUHS in the development, marketing, advertising, patent-acquisition, and capitalization of genomic research and clinical trial studies were not performed as the rendering of professional healthcare services, but rather were performed in the furtherance of multi-million dollar financial gain and institutionalized and corporate profits.

292. Duke University and/or DUHS's conduct, violations of safety statutes, and breach of fiduciary duty, constructive fraud, and actual fraud constitute unfair or deceptive acts or practices and unfair methods of competition in or affecting commerce in North Carolina in violation of N.C. Gen. Stat. § 75-1.1.

293. As a direct and proximate result of Duke University and/or DUHS 's unfair or deceptive trade practices, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from Duke University and/or DUHS's unfair or deceptive trade practices. The Plaintiffs are also each entitled to recover treble damages and attorney's fees, under N.C. Gen. Stat.§§ 75-16 and 16.1.

FIFTEENTH CLAIM FOR RELIEF
Intentional and/or Negligent Infliction of Emotional Distress
(All Defendants)

294. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

295. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused Plaintiffs severe emotional distress.

296. The conduct of Defendants in making false statements to Plaintiffs, knowing that he/she would rely on these statements in deciding whether to participate in the clinical trial at issue and to accept the chemotherapy medication treatment offered by the physician as part of the clinical trial at issue, which ultimately and directly resulted in Plaintiffs' injuries, has caused emotional harm to Plaintiffs, and was extreme and outrageous.

297. Plaintiffs who are living have suffered severe emotional distress, including but not limited to depression and/or anxiety as a result of the conduct of the Defendants.

298. Defendants' actions were willful and/or reckless thus entitling Plaintiff to punitive damages.

299. As a direct and proximate result of the Defendants' actions, the plaintiff's intestate or plaintiff individually suffered severe emotional distress and mental injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference. The Plaintiffs are entitled to recover damages in excess of $10,000.00 for injuries sustained, and the resulting medical expenses as applicable, all proximately resulting from and caused by the Defendants' conduct.

SIXTEENTH CLAIM FOR RELIEF
Loss of Chance
(All Defendants)

300. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

301. Defendants engaged in the above-described conduct, which reduced the Plaintiffs' likelihood of surviving his/her cancer or likelihood of experiencing a positive response to the chemotherapy regimen.

302. Plaintiffs have suffered a drastic loss of chance in his/her ability to survive his/her cancer as a result of the conduct of the Defendants, or ability to achieve a positive response to the chemotherapy regimen. This physical harm was a direct and proximate result of the actions of the Defendants.

303. As a direct and proximate result of the Defendants' actions, the plaintiff's intestate or plaintiff individually suffered damages and loss of chance, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for damages proximately resulting to them as a result of defendant's conduct.

SEVENTEENTH CLAIM FOR RELIEF
Battery
(Duke University and/or DUHS)

304. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

305. Defendant Duke University and/or DUHS by and through its administrative and managerial officials and officers, physicians, staff agents, and other employees, failed to inform Plaintiffs of the risks of all treatment, care, therapy and procedures performed upon her/him, and failed to accurately inform Plaintiffs of the true academic credentials of Potti, one of the lead investigators involved in the very cancer research underlying the clinical trials, so as to afford

Plaintiffs the opportunity to make an informed decision as to the performance of said treatments and procedures, and the credibility of one of the clinical trials lead investigators.

306. Defendant Duke University and/or DUHS by and through its administrative and managerial officials and officers, physicians, staff, agents, and other employees failed to inform Plaintiffs of the errors, false, fraudulent and incorrect information in the data upon which the clinical trials were based, or that the information represented to them in the clinical trials was incorrect, false and fraudulent, so as to afford Plaintiffs the opportunity to make an informed decision as to his/her participation in the clinical trials at issue.

307. The lack of informed consent includes, but is not limited to:

a) failing to inform the Plaintiffs that the data upon which the clinical trial at issue was based was filled with errors;
b) failing to inform the Plaintiffs that Potti actively lied regarding his credentials and accolades in sponsorship applications;
c) failing to inform the Plaintiffs that he/she may not actually receive the "best" chemotherapy treatment as shown by the LSM model;
d) misrepresenting the fact that the Plaintiffs may not receive the standard chemotherapy for his/her cancer;
e) failing to adequately disclose the extent to which the Defendants had conflicts of interest;
f) failing to adequately disclose the financial interest that Duke University and/or DUHS, Drs. Potti, Nevins, other physicians and administrative and managerial officials and officers had in relation to the study;
g) failing to adequately disclose the inherent conflicts of interest among the members of the Duke IRB and other investigational bodies created to monitor the data and safety surrounding the clinical trials;
h) failing to inform the Plaintiffs that outside researchers had raised serious issues and concerns regarding the cancer research and issue and the safety of the clinical trials;
i) failing to inform the Plaintiffs that the "external panel" and the IRB's findings and "validation" had been improperly based upon a lack of information provided to same by Drs. Cuffe, Kornbluth and Harrelson;
j) allowing the Plaintiffs to participate in the clinical trial after the trial should have been terminated;
k) by other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

308. Between 2006 and 2010, the Plaintiffs reviewed documents and had discussions with their physicians, which purportedly were to provide certain information, both expressly and impliedly, necessary to make an informed decision as to whether Plaintiffs were going to take part in and were appropriate candidates for the clinical cancer trial at issue.

309. Such documents and discussions, both expressly and impliedly, were materially misleading and deceptive because they failed to disclose true and correct information and instead contained misinformation, lies and false information.

310. The effects of such misrepresentations and nondisclosure were that the Plaintiffs believed the risks of his/her participation in the clinical cancer trial at issue were minimal; he/she would receive the "best" chemotherapy and treatment based upon his/her participation in the trial; that if he/she was receiving chemotherapy treatment outside of the clinical trial, he/she would receive standard chemotherapy treatment; that the potential benefits of his/her participation to the future treatment of other similarly situation patients in the future would be enormous; and that the academic credentials of all of the researchers, investigators and doctors involved in the research underlying the clinical trials were valid and not fraudulently reported.

311. As a result of the intentional tortious conduct of these Defendants, and each of them respectively, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, Plaintiffs suffered the infliction of harmful and/or offensive contacts upon their person without their informed consent, including but not limited to an unnecessary biopsy, and invasive treatments, procedures and tests required by their participation in the Cancer Clinical trial.

312. As a direct and proximate result of the intentional tortious conduct of these Defendants, , and each of them respectively, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress. The plaintiffs are each entitled to recover in excess of $10,000.00 for injuries proximately resulting to them from defendants' actions and resulting battery.

EIGHTEENTH CLAIM FOR RELIEF
LOSS OF CONSORTIUM

313. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

314. At all times referred to in this complaint, Plaintiff's intestate and Plaintiff individually were lawfully married as husband and wife and had a marital relationship that included marital services, society, affection, companionship, and sexual relations.

315. The injuries sustained by Plaintiff's intestate caused a loss or disruption of one or more of the elements of marital consortium listed above, and Plaintiff individually, as the spouse of Plaintiff's intestate, has suffered a loss of consortium as a result of the injuries sustained by Plaintiff's intestate as a proximate result of the acts and omissions of the defendants.

316. As a direct and proximate result of the Defendants' actions and conduct as described herein, plaintiff individually suffered damages for loss of consortium as applicable and as identified in the attached Exhibits **#** 1 through **#** 8. The plaintiffs, as identified in the attached Exhibits #1 through #8, are therefore each entitled to damages for loss of consortium in excess of $10,000 from the defendants.

NINETEENTH CLAIM FOR RELIEF
Survival Action

317. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

318. As a direct and proximate cause of the conduct of the defendants, and the breaches of duty and standards of care as described herein, the plaintiffs' intestate suffered physical, mental and financial injuries and damages, which caused great worry, anxiety, apprehension and emotional distress. The plaintiff is entitled to recover in excess of $10,000.00 for injuries proximately resulting to plaintiff's intestate from the defendants' negligence and conduct as outlined herein.

TWENTIETH CLAIM FOR RELIEF
Punitive Damages
(Individual Defendants)

319. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

320. Potti, Nevins, Dr. Marcom, Mr. Barry, Mr. Ginsburg, Dr. Cuffe, Dr. Kornbluth, Dr. Harrelson, Dr. Marcom, Dr. Vlahovic, Dr. Garst and Dr. Ready and others yet unknown, engaged in conduct and omissions which constituted willful and wanton misconduct and further constituted conscious and intentional disregard of and indifference to the rights and safety of the Plaintiffs and others similarly situated.

321. The wrongful acts, omissions, and conduct of the above-mentioned physicians and other actors alleged in the preceding paragraphs of this Complaint also constitute a conscious and intentional disregard of and indifference to their responsibility to carry out duties imposed by law or contract which were necessary for the safety of the patients, which the above-mentioned physicians and other actors knew or should have known was reasonably likely to result in injury, damage or other harm to the Plaintiffs and others similarly situated.

322. The above-mentioned physicians and other actors' willful and wanton conduct include the following:

a. repeatedly ignoring complaints of errors and missing data in the research published by the Duke cancer researchers;
b. repeatedly ignoring complaints of possible dangers to patients in the clinical trials based upon issues and questions raised by outside researchers;
c. misrepresenting the credentials of Dr. Potti in applications to the U.S. government and other non-governmental organizations and in Duke University and/or DUHS publications;
d. making deceptive and misleading public statements about the research at issue and the clinical trials at issue, as well as of the patients' potential and real harm as a result;
e. breaching their duty to report to the North Carolina Department of Health and Human Services the incidents leading to the filing of this lawsuit, which it was legally required to do, in order to avoid regulatory scrutiny of its negligence and subsequent willful and wanton misconduct;
f. breaching their duty to obtain FDA approval of the clinical trials;

g. breaching their duty to perform basic mathematical and statistical calculations to determine if the research at issue was valid and supported the clinical trials at issue;
h. failing to provide full and complete data and information both to all of the members of the IRB and to the "external panel";
i. failing to protect patients in the clinical trials;
j. concealing from the Plaintiffs, full and complete information regarding his/her exposure to medication in the form of improper chemotherapy treatment;
k. actively providing false and incorrect information and acting in a cover-up and fraud in the concealment of the true nature of the research which formed the basis of the clinical trials;
l. actively pursuing and participating in fraud and concealment in order to gain financial incentives, notoriety and accolades;
m. actively promoting clinical trials that were potentially and actually dangerous and harmful to patients;
n. failing to obtain a true informed consent from the Plaintiffs – an informed consent absent lies, false information and fraud; and,
o. engaging in such other and further breaches constituting extreme and outrageous conduct by the above-mentioned physicians and other actors as will be shown at the trial of this matter after discovery and further investigation. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

323. The above-mentioned physicians and other actors knew or should have known that these actions would exacerbate and aggravate the harms done to the Plaintiffs, as well as unnecessarily harm other patients, whose improper chemotherapy treatment occurred after the cancer research at issue had been shown as substantially flawed, as is set forth herein and incorporated as if fully set forth.

324. An award of punitive damages is warranted to punish the above-mentioned physicians and other actors' egregious conduct and to deter the above-mentioned physicians and other actors and others from engaging in similar conduct which is likely to cause industry-wide and irreparable damage to the noble pursuits of scientific cancer research, as well as human subject clinical trials, for years to come.

325. The Plaintiffs object to the limitations on recovery of punitive damages, and to the requirement that, in the case of corporate defendants, the conduct complained of be either condoned by or participated in by managers or officers of the corporate entity, all contained in

the North Carolina Punitive Damages Statute, N.C.G.S. §§ 1D-1 through 1D-50, and allege, in compliance with N.C. Rule of Civil Procedure 11(a), that they have a good faith argument that existing appellate law on the limitations on recovery under the existing statutory scheme should be reversed because these limitations violate the Plaintiffs' rights of due process of law, of equal protection under the law, of the right to open courts, of access to the courts, and of the right to a jury trial (in violation of the United States and North Carolina Constitutions) and, further, that the Punitive Damages Statute is an unconstitutional violation of the following: (A) Amendment VII, IX, and XIV of the United States Constitution; (B) Article I, Sections 1, 6, 7, 14, 18, 19, 25, 35, and 36; and Article IV, Sections 1 and 13 of the North Carolina Constitution.

326. As a direct and proximate result of defendant's willful and wanton misconduct, the plaintiff's intestate or plaintiff individually suffered injuries and damages. The plaintiffs, as identified in the attached Exhibits #1 through #8, which are herein incorporated by reference, are entitled to recover punitive damages in excess of $10,000.00 all proximately resulting from and caused by defendant's willful and wanton misconduct as described herein.

TWENTY-FIRST CLAIM FOR RELIEF
Punitive Damages
(Duke University and/or Duke University Health System, Inc.)

327. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

328. Duke University and/or DUHS, through its agents and employees, and with the condonation and/or participation of its managerial employees, Drs. Cuffe, Kornbluth and Harrelson, and its other employees, Nevins, Mr. Ginsburg and Potti, others above-mentioned, and others yet unknown, engaged in conduct and omissions which constituted willful and wanton misconduct and further constituted conscious and intentional disregard of and indifference to the rights and safety of the Plaintiffs and others similarly situated.

329. The wrongful acts, omissions, and conduct of Duke University and/or DUHS alleged in the preceding paragraphs of this complaint also constitute a conscious and intentional disregard of and indifference to its responsibility to carry out duties imposed by law or contract which were necessary for the safety of it patients, which Duke University and/or DUHS knew or

should have known was reasonably likely to result in injury, damage or other harm to the Plaintiffs and others similarly situated.

330. Duke University and/or DUHS's willful and wanton conduct includes the following:

a. repeatedly ignoring complaints of errors and missing data in the research published by the Duke cancer researchers;
b. repeatedly ignoring complaints of possible dangers to patients in the clinical trials based upon issues and questions raised by outside researchers;
c. misrepresenting the credentials of Dr. Potti in applications to the U.S. government and other non-governmental organizations and in Duke University and/or DUHS publications;
d. making deceptive and misleading public statements about the research at issue and the clinical trials at issue, as well as of the patients' potential and real harm as a result;
e. breaching its duty to report to the North Carolina Department of Health and Human Services the incidents leading to the filing of this lawsuit, which it was legally required to do, in order to avoid regulatory scrutiny of its negligence and subsequent willful and wanton misconduct;
f. breaching its duty to obtain FDA approval of the clinical trials;
g. breaching its duty to perform basic mathematical and statistical calculations to determine if the research at issue was valid and supported the clinical trials at issue;
h. failing to provide full and complete data and information both to all of the members of the IRB and to the "external panel";
i. failing to protect patients in the clinical trials;
j. concealing from the Plaintiffs, full and complete information regarding his/her exposure to medication in the form of improper chemotherapy treatment;
k. failing to obtain a true informed consent from the Plaintiffs – an informed consent absent lies, false information and fraud; and,
l. engaging in such other and further breaches constituting extreme and outrageous conduct by Duke University and/or DUHS as will be shown at the trial of this matter after discovery and further investigation. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

331. Duke University and/or DUHS's managerial employees and leadership and other employees knew or should have known that these actions would exacerbate and aggravate the

harms done to the Plaintiffs, as well as unnecessarily harm other patients, whose improper chemotherapy treatment occurred after the cancer research at issue had been shown as substantially flawed, as is set forth herein and incorporated as if fully set forth.

332. An award of punitive damages is warranted to punish Duke University and/or DUHS's egregious conduct and to deter Duke University and/or DUHS and others from engaging in similar conduct which is likely to cause industry-wide and irreparable damage to the noble pursuits of scientific cancer research, as well as human subject clinical trials, for years to come.

333. The Plaintiffs object to the limitations on recovery of punitive damages, and to the requirement that, in the case of corporate defendants, the conduct complained of be either condoned by or participated in by managers or officers of the corporate entity, all contained in the North Carolina Punitive Damages Statute, N.C.G.S. §§ 1D-1 through 1D-50, and allege, in compliance with N.C. Rule of Civil Procedure 11(a), that they have a good faith argument that existing appellate law on the limitations on recovery under the existing statutory scheme should be reversed because these limitations violate the Plaintiffs' rights of due process of law, of equal protection under the law, of the right to open courts, of access to the courts, and of the right to a jury trial (in violation of the United States and North Carolina Constitutions) and, further, that the Punitive Damages Statute is an unconstitutional violation of the following: (A) Amendment VII, IX, and XIV of the United States Constitution; (B) Article I, Sections 1, 6, 7, 14, 18, 19, 25, 35, and 36; and Article IV, Sections 1 and 13 of the North Carolina Constitution.

334. As a direct and proximate result of Duke University and/or DUHS's willful and wanton misconduct, the plaintiff's intestate or plaintiff individually suffered injuries and damages. The Plaintiffs, as identified in the attached Exhibits #1 through #8, which are herein incorporated by reference, are entitled to recover punitive damages in excess of $10,000.00 all proximately resulting from and caused by Duke University and/or DUHS's willful and wanton misconduct as described herein.

TWENTY-SECOND CLAIM FOR RELIEF
Civil Conspiracy and Obstruction of Justice
(Individual defendants and
Duke University and/or Duke University Health System, Inc.)

335. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

336. The defendants individually and Duke University and/or DUHS, by and through their separate and respective agents, servants, deans, representatives, physicians, nurses, staff, researchers, and other employees:

a) had exclusive possession and control of all of the supporting data for the science upon which the clinical trials were based;
b) were fully informed that outside researchers had raised serious issues and concerns regarding the cancer research and the safety of the clinical trials;
c) had conflicts of interest because of their pecuniary interest in corporations formed to market and profit from the sale of tests and testing resulting from the scientific work proven by the clinical trials;
d) had conflicts of interest because of their pecuniary interest in patents formed to market and profit from the sale of the tests and testing resulting from the scientific work proven by the clinical trials;
e) had conflict of interest because of marital relationships between individuals involved in the investigation of the faulty science and accusations of misconduct involving reputation and financial incentives;
f) had the joint desire to protect the reputation of Duke University and/or DUHS and the individuals who were publishing and were an active part of the entire issue surrounding the cancer trials and its potential failures;
g) had the joint desire to protect the financial position of Duke University and/or DUHS and the individuals who were publishing and were an active part of the obtaining financial incentives in the forms of grants from public and private agencies and the US government from which the institutions and individuals benefited directly.

337. The defendants individually and Duke University and/or DUHS, by and through their separate and respective agents, servants, deans, representatives, physicians, nurses, staff, researchers, and other employees were well aware of potential legal claims by patients who were participating in a clinical trial based on fraudulent and inaccurate science putting them at risk of

bodily harm and/or receiving inappropriate chemotherapy and/or causing harmful impact to the pecuniary interest of the defendants.

338. Because of exclusive knowledge and control of the supporting data and fear of consequences of truthful disclosure, the defendants individually and Duke University and/or DUHS, by and through their separate and respective agents, servants, deans, representatives, physicians, nurses, staff, researchers, and other employees, willfully and knowingly formed, participated, or engaged in a civil conspiracy and course of deceptive conduct that was designed to minimize potential exposure to legal claims by patients who had been exposed to unnecessary chemotherapy medication, to protect its reputation and its proprietary interests at the expense of plaintiffs patients' safety, all in furtherance of its conspiracy to obstruct justice, by:

a) controlling the information delivered to the "external panel" in order to ensure a validation of the science all of which was improperly based upon a lack of information provided to the "external panel" specifically by Drs. Cuffe, Kornbluth and Harrelson and others;
b) failing to perform simple, computational calculations that would have revealed that the Duke cancer researchers' data had serious errors and issues;
c) consulting with and obtaining the permission of one of the lead investigators of the clinical trials and co-author of the challenged science with regard to how the investigation of the charges of invalid science were to be handled;
d) limiting the "external panel" to review of only a portion of the science and neglecting to direct the panel to investigate the underlying and most important part of the accusations of invalid and improper science;
e) publishing to the public at large a summary of the panel's report which was misleading and deceptive and false and using that summary as the basis for the continuation of the dangerous clinical trials;
f) failing to conduct a complete and open investigation and evaluation of the entire clinical trial issue and instead created an atmosphere of distrust, retribution and intimidation in the labs and with the staff that could have revealed what was known or should have been known and when it was or should have been known;
g) instructing staff and researchers in the Potti and Nevins lab to not engage in discussions, investigations or in any way participate in shedding light on the totality of the scandal created by the revelation that Potti had falsified his credentials;
h) misrepresenting and minimizing the extent and severity of the experimentation based on faulty science;

i) suppressing information to the public that the plaintiffs and the public had a right to know;

j) sending a misleading and deceptive letter to the plaintiffs minimizing and misstating the extent and severity of the problem with the faulty science and the potential risk to the plaintiffs;

k) failing to adequately or fully inform all persons who participated or received any invasive procedure such as biopsies, other surgical procedures, or other tests used to qualify them as participants, or who received chemotherapy and/or radiation or any other treatment regimen or were any way a part of or a participant in the clinical trials, of the fact that the consent obtained from them was invalid and false and that they had been harmed by said participation;

l) and by other wrongful acts and omissions as may be determined during the investigation or discovery in this litigation and shown at the trial of this matter. Plaintiffs move to amend to conform to the evidence developed in discovery and at the trial of this matter.

339. The above alleged acts were done pursuant to an agreement and common scheme between the defendants individually and Duke University and/or DUHS, by and through their separate and respective agents, servants, deans, representatives, physicians, nurses, staff, researchers, and other employees to commit the above unlawful acts and/or to commit the above acts in an unlawful way.

340. These actions caused the plaintiffs delays in treatment and diagnosis, submissions to improper chemotherapy regimens, submission to unnecessary biopsy procedures, and/or significant emotional distress and mental pain and physical suffering. In addition the, self-serving statements by Duke University and/or DUHS , in furtherance of their civil conspiracy, to the public, to the plaintiffs and other patients, and to the physicians and surgeons of plaintiffs, minimized and misrepresented their present and future risk of further harm, enhanced their mental anguish, and was designed to and/or had the effect of discouraging plaintiffs from pursuing legal remedies.

341. Access to information would have allowed plaintiffs to perform other and additional tests to examine and define their present and future risk of further harm or benefits. This deprivation harmed the plaintiff patients not only from a medical perspective but also hindered their abilities to prove their damages in a court of law.

342. The mismanagement of data and persons, misrepresentation regarding the evidence and risks of harm to the plaintiffs, and other acts designed to minimize Duke University and/or DUHS' exposure to justified litigation and claims and to discourage litigants from proceeding, were unlawful and obstructed and impeded the plaintiffs' access to public justice, by delaying and obstructing their access to information which would have allowed them to more accurately assess their injuries and predict their future impairments.

343. Duke University and/or DUHS has published data online and then removed it and not made it available to any public source and is believed to have been destroyed and if so, Plaintiffs are entitled to a spoliation instruction and other relief at the trial of this matter as a result of the defendants' conduct in obstruction of public justice.

344. As a direct and proximate result of the conduct as described herein, the plaintiff's intestate or plaintiff individually suffered physical, mental and financial injuries and damages, as are identified in the attached Exhibits # 1 through # 8, which are herein incorporated by reference, and which caused plaintiff's intestate or plaintiff individually great worry, anxiety, apprehension and emotional distress.. The Plaintiffs are entitled to recover damages in excess of $10,000.00 for all damages proximately resulting from and caused by the civil conspiracy and obstruction of justice committed by all defendants as outlined herein.

TWENTY THIRD CLAIM FOR RELIEF
Vicarious Liability
(Duke Private Diagnostic Clinic, PLLC)

345. Plaintiff re-alleges each and every preceding paragraph of this Complaint and incorporates each by reference as if fully set forth herein.

346. At all times relevant hereto, each and every act or omission of the Individual Defendants Nevins, Potti, Marcom, Cuffe, Kornbluth and Harrelson alleged herein above, occurred while said Defendants were performing duties as agents and/or employees of Defendant Private Diagnostic Clinic, PLLC. The above-referenced acts and omissions of Defendants Nevins, Potti, Marcom, Cuffe, Kornbluth and Harrelson occurred in the regular course and scope of their agency and/or employment with Defendant Private Diagnostic Clinic, PLLC, and each and every act or omission of said Defendants is imputed to Defendant Private Diagnostic Clinic, PLLC under the doctrines of imputed liability, agency and *respondeat superior*.

TWENTY-FORTH CLAIM FOR RELIEF
CONCURRING AND COMBINED NEGLIGENCE
(ALL DEFENDANTS)

347. Plaintiffs re-allege each and every preceding paragraph of this Complaint and incorporate each by reference as if fully set forth herein.

348. The negligence of each Defendant, set forth elsewhere herein in more detail, was a direct, proximate, and independent cause of plaintiffs' injuries and damage.

349. Additionally, the separate and independent acts or omissions of each defendant concurred and combined to produce plaintiffs' injuries and damage, and the conduct of each defendant is a proximate cause of those injuries.

350. The independent negligent acts or omissions by each defendant concurred to produce the plaintiffs' injuries and the conduct of each is a proximate cause, even assuming arguendo that one defendant may have been more or less negligent than another, which plaintiffs' deny but expect may be alleged at some point by one or more defendants.

351. Defendants are jointly and severally liable for Plaintiffs' injuries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that they each have and recover of the Defendants jointly and severally:

1. Judgment for damages in an amount in excess of ten thousand dollars ($10,000.00) for compensatory damages against all Defendants;

2. Judgment for damages in an amount in excess of ten thousand dollars ($10,000.00) for punitive damages against all Defendants;

3. Treble damages and attorneys' fees from Duke University and/or DUHS, under the North Carolina Unfair and Deceptive Trade Practice Act, in an amount in excess of ten thousand dollars ($10,000.00)

4. Interest as provided by law;

5. Costs of this action, including expert witness fees, filing fees and other allowable costs incurred in connection with this claim;

6. Attorneys' fees, where applicable as provided by law;

7. Trial by jury on all issues so triable herein; and

8. Such other and further relief as the Court deems just and proper.

This the 7th day of September, 2011.

Thomas W. Henson, Jr.
N.C. State Bar No. 16669
Attorneys for Plaintiffs
2501 Blue Ridge Road, Suite 390
Raleigh, North Carolina 27607
Tel: (919) 781-1107
Fax: (919) 781-8048

EXHIBIT 1
Claim of Plaintiff, Richard Aiken

1. Plaintiff, Richard Aiken is a citizen and resident of Richmond County, North Carolina and is under no legal disability.

2. In 2009, Richard Aiken was diagnosed with lung cancer, Stage IB, T2a, N0 adenocarcinoma.

3. In 2010, Richard Aiken was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Directed Cisplatin Based Chemotherapy with Either Vinorelbine or Pemetrexed for the Adjuvant Treatment of Early Stage Non-Small Cell Lung Cancer (NSCLC) in Patients Using Genomic Expression Profiles of Chemotherapy Sensitivity to Guide Therapy".

4. At the time of his participation in the clinical trials at issue, Plaintiff was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

5. At the time of his participation in the clinical trials at issue, Plaintiff was informed by Duke University and/or DUHS that he would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Plaintiff a higher likelihood of favorable response.

6. At the time of his participation in the clinical trials at issue, Plaintiff was informed and believed that his participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Plaintiff with a similar cancer type would normally receive. Plaintiff was informed by Duke University and/or DUHS that the cancer clinical trial would offer his cancer a medical treatment that was better than what he would have received without participation in the clinical trial.

7. The chemotherapy that Plaintiff paid for and received as a part of the Duke University and/or DUHS clinical trial was not standard of medical care, nor the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for his cancer that had higher likelihood of favorable response, nor was it better than what Richard Aiken would have received if he had not participated in the clinical trial.

8. The participation of the Plaintiff was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Plaintiff been properly and fully informed, he would have chosen not to participate in the clinical trial.

9. As a result of the conduct of the defendants, Plaintiff was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

10. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Richard Aiken was mentally and physically injured and damaged as a

result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Richard Aiken was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Richard Aiken has incurred medical expenses for medical and psychological treatment, medications, and/or therapy.

13. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, upon information and belief, the injuries sustained by Richard Aiken will require ongoing medical treatment and Richard Aiken will incur future medical expenses for treatment, medications, and/or therapy.

14. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, the injuries to Richard Aiken have caused injuries including mental and physical pain and suffering, loss of enjoyment of life, and/or loss of earnings and loss of future earning capacity, and/or activation or reactivation of a disease or aggravation of an existing condition.

15. Plaintiff hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief- Loss of Consortium and the 19th Claim for Relief – Survival Action.

16. That the plaintiff Richard Aiken have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

17. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 2
Claim of Plaintiff, Jean K. Carroll,
as Executrix of the Estate of Harold G. Carroll
and Plaintiff, Jean K. Carroll, Individually

1. Plaintiff, Jean K. Carroll was appointed Executrix of the Estate of Harold G. Carroll, deceased, by the Clerk of Superior Court in Wake County, North Carolina, and is duly qualified and is now acting as Executrix in this action. Jean K. Carroll is under no legal disability.

2. Plaintiff Jean K. Carroll, individually, is a citizen and resident of Wake County, North Carolina.

3. In 2010, Plaintiff's intestate, Harold G. Carroll, was diagnosed with lung cancer, Stage IV T3N1M1 adenocarcinoma.

4. In 2010, Harold G. Carroll was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy.

5. At the time of his participation in the clinical trials at issue, Harold G. Carroll was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

6. At the time of his participation in the clinical trials at issue, Harold G. Carroll was informed by Duke University and/or DUHS that he would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Plaintiff a higher likelihood of favorable response.

7. At the time of his participation in the clinical trials at issue, Harold G. Carroll was informed and believed that his participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Harold G. Carroll, with a similar cancer type would normally receive. Harold G. Carroll was informed by Duke University and/or DUHS that the cancer clinical trial would offer his cancer a medical treatment that was better than what he would have received without participation in the clinical trial.

8. The chemotherapy that Harold G. Carroll paid for and received as a part of the Duke University and/or DUHS clinical trial was not the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for his cancer that had higher likelihood of favorable response, nor was it better than what Harold G. Carroll would have received if he had not participated in the clinical trial.

9. The participation of Harold G. Carroll was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Harold G. Carroll been properly and fully informed, he would have chosen not to participate in the clinical trial.

10. As a result of the conduct of the defendants, Harold G. Carroll was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Harold G. Carroll was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Harold G. Carroll was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

13. That the plaintiff Jean K. Carroll, as Executrix of the Estate of Harold G. Carroll, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief- Loss of Consortium.

14. That the plaintiff Jean K. Carroll, as Executrix of the Estate of Harold G. Carroll shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

15. At all times referred to in this complaint, Harold G. Carroll and Jean K. Carroll were lawfully married as husband and wife and had a marital relationship that included marital services, society, affection, companionship, and sexual relations.

16. The injuries sustained by Harold G. Carroll caused a loss or disruption of one or more of the elements of marital consortium listed above, and Jean K. Carroll suffered a loss of consortium as a result of the injuries sustained by Harold G. Carroll as a proximate result of the acts and omissions of the defendants.

17. Plaintiff, individually, hereby claims damages under the 18th Claim for Relief-Loss of Consortium, as set out in the attached complaint.

18. That the plaintiff Jean K. Carroll, individually, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

19. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 3
Claim of Plaintiff, Peggy Cox,
as Administratrix of the Estate of Paul F. Cox,
and Plaintiff, Peggy Cox, Individually

1. Plaintiff, Peggy Cox was appointed Administratrix of the Estate of Paul F. Cox, deceased, by the Clerk of Superior Court in Raleigh County, West Virginia, and is duly qualified and is now acting as Administratrix in this action. Peggy Cox is under no legal disability.

2. Plaintiff Peggy Cox, individually, is a citizen and resident of Raleigh County, West Virginia.

3. In 2008, Plaintiff's intestate, Paul F. Cox, was diagnosed with lung cancer, Stage IIB, either T2N0M0 (Stage IB) or T2N1M0 (Stage IIB) 5cm squamous cell cancer of the left upper lobe.

4. In 2009, Paul F. Cox was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Directed Cisplatin Based Chemotherapy with Either Vinorelbine or Pemetrexed for the Adjuvant Treatment of Early Stage Non-Small Cell Lung Cancer (NSCLC) in Patients Using Genomic Expression Profiles of Chemotherapy Sensitivity to Guide Therapy".

5. At the time of his participation in the clinical trials at issue, Paul F. Cox was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

6. At the time of his participation in the clinical trials at issue, Paul F. Cox was informed by Duke University and/or DUHS that he would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give him a higher likelihood of favorable response.

7. At the time of his participation in the clinical trials at issue, Paul F. Cox was informed and believed that his participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Paul F. Cox, with a similar cancer type would normally receive. Paul F. Cox was informed by Duke University and/or DUHS that the cancer clinical trial would offer his cancer a medical treatment that was better than what he would have received without participation in the clinical trial.

8. The chemotherapy that Paul F. Cox paid for and received as a part of the Duke University and/or DUHS clinical trial was not the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for his cancer that had higher likelihood of favorable response, nor was it better than what Harold G. Carroll would have received if he had not participated in the clinical trial.

9. The participation of Paul F. Cox was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Paul F. Cox been properly and fully informed, he would have chosen not to participate in the clinical trial.

10. As a result of the conduct of the defendants, Paul F. Cox was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Paul F. Cox was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Paul F. Cox was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

13. That the plaintiff, Peggy Cox, as Administratrix of the Estate of Paul F. Cox, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief - Loss of Consortium.

14. That the plaintiff, Peggy Cox, as Administratrix of the Estate of Paul F. Cox, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

15. At all times referred to in this complaint, Paul F. Cox and Peggy Cox were lawfully married as husband and wife and had a marital relationship that included marital services, society, affection, companionship, and sexual relations.

16. The injuries sustained by Paul F. Cox caused a loss or disruption of one or more of the elements of marital consortium listed above, and Peggy Cox suffered a loss of consortium as a result of the injuries sustained by Paul F. Cox as a proximate result of the acts and omissions of the defendants.

17. Plaintiff, individually, hereby claims damages under the 18th Claim for Relief-Loss of Consortium, as set out in the attached complaint.

18. That the plaintiff Peggy Cox, individually, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

19. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 4
Claim of Plaintiff, Helene F. Fligel

1. Plaintiff, Helene F. Fligel is a citizen and resident of Buncombe County, North Carolina and is under no legal disability.

2. In 2010, Helene F. Fligel was diagnosed with lung cancer, Stage IV T1N3M1 adenocarcinoma.

3. In 2010, Helene F. Fligel was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy".

4. At the time of her participation in the clinical trials at issue, Plaintiff was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

5. At the time of her participation in the clinical trials at issue, Plaintiff was informed by Duke University and/or DUHS that she would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Plaintiff a higher likelihood of favorable response.

6. At the time of her participation in the clinical trials at issue, Plaintiff was informed and believed that her participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Plaintiff with a similar cancer type would normally receive. Plaintiff was informed by Duke University and/or DUHS that the cancer clinical trial would offer her cancer a medical treatment that was better than what she would have received without participation in the clinical trial.

7. The chemotherapy that Helene F. Fligel paid for and received as a part of the Duke University and/or DUHS clinical trial was not the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for her cancer that had higher likelihood of favorable response, nor was it better than what she would have received if she had not participated in the clinical trial.

8. The participation of the Plaintiff was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had plaintiff been properly and fully informed, she would have chosen not to participate in the clinical trial.

9. As a result of the conduct of the defendants, Plaintiff was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

10. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Helene F. Fligel was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Helene F. Fligel was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, the injuries to Helene F. Fligel have caused injuries including mental and physical pain and suffering, and loss of enjoyment of life.

13. Plaintiff hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief- Loss of Consortium and the 19th Claim for Relief – Survival Action.

14. That the plaintiff Helene F. Fligel have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

15. All claims set out herein are by reference incorporated and made a part of the attached complaint and all claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 5
Claim of Plaintiff, Jason Gannon,
as Personal Representative of the
Estate of Jennifer L. Gannon

1. Plaintiff, Jason Gannon was appointed Personal Representative of the Estate of Jennifer L. Gannon, deceased, by the Honorable Darlene A. O'Brien in Washtenaw County, Michigan, and is duly qualified and is now acting as Personal Representative in this action. Jason Gannon is under no legal disability.

2. In 2008, Plaintiff's intestate, Jennifer L. Gannon, was diagnosed with lung cancer, Stage IV.

3. In 2008, Jennifer L. Gannon was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy".

4. At the time of her participation in the clinical trials at issue, Jennifer L. Gannon was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

5. At the time of her participation in the clinical trials at issue, Jennifer L. Gannon was informed by Duke University and/or DUHS that she would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Jennifer L. Gannon a higher likelihood of favorable response.

6. At the time of his participation in the clinical trials at issue, Jennifer L. Gannon was informed and believed that her participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Jennifer L. Gannon with a similar cancer type would normally receive. Jennifer L. Gannon was informed by Duke University and/or DUHS that the cancer clinical trial would offer her cancer a medical treatment that was better than what she would have received without participation in the clinical trial.

7. The chemotherapy that Jennifer L. Gannon paid for and received as a part of the Duke University and/or DUHS clinical trial was not the standard of medical care, nor the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for her cancer that had higher likelihood of favorable response, nor was it better than what Jennifer L. Gannon would have received if she had not participated in the clinical trial

8. The participation of Jennifer L. Gannon was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Jennifer L. Gannon been properly and fully informed, she would have chosen not to participate in the clinical trial.

9. As a result of the conduct of the defendants, Jennifer L. Gannon was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

10. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Jennifer L. Gannon was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Jennifer L. Gannon was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

12. That the plaintiff Jason Gannon, as Personal Representative of the Estate of Jennifer Gannon, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief - Loss of Consortium.

13. That the plaintiff Jason Gannon, as Personal Representative of the Estate of Jennifer Gannon, have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

14. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 6
Claim of Plaintiff, John Haddock,
as Personal Representative of the
Estate of Karen Heath

1. Plaintiff, John Haddock was appointed Executor of the Estate of Karen Heath, deceased, by the Clerk of Superior Court in Craven County, North Carolina, and is duly qualified and is now acting as Executor in this action. John Haddock is under no legal disability.

2. In 2010, Plaintiff's intestate, Karen Heath, was diagnosed with lung cancer, Stage IV adenocarcinoma with brain and liver metastases.

3. In 2010, Karen Health was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy".

4. At the time of her participation in the clinical trials at issue, Karen Heath was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

5. At the time of her participation in the clinical trials at issue, Karen Heath was informed by Duke University and/or DUHS that she would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Karen Heath a higher likelihood of favorable response.

6. At the time of her participation in the clinical trials at issue, Karen Heath was informed and believed that her participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Karen Heath with a similar cancer type would normally receive. Karen Heath was informed by Duke University and/or DUHS that the cancer clinical trial would offer her cancer a medical treatment that was better than what she would have received without participation in the clinical trial.

7. The chemotherapy that Karen Heath paid for and received as a part of the Duke University and/or DUHS clinical trial was not the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for her cancer that had higher likelihood of favorable response, nor was it better than what Karen Heath would have received if she had not participated in the clinical trial.

8. The participation of the Karen Heath was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Karen Heath been properly and fully informed, she would have chosen not to participate in the clinical trial.

9. As a result of the conduct of the defendants, Karen Heath was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

10. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Karen Heath was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Karen Heath was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

12. That the plaintiff John Haddock, as Personal Representative of the Estate of Karen Heath, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief - Loss of Consortium.

13. That the plaintiff John Haddock, as Personal Representative of the Estate of Karen Heath, have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

14. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 7
Claim of Plaintiff, Walter Jacobs,
as Executor of the Estate of Juliet J. Jacobs,
and Plaintiff, Walter Jacobs, Individually

1. Plaintiff, Walter Jacobs was appointed Executor of the Estate of Juliet J. Jacobs, deceased, by the Clerk of Superior Court in Orange County, North Carolina, and is duly qualified and is now acting as Executor in this action. Walter Jacobs is under no legal disability.

2. Plaintiff Walter Jacobs, individually, is a citizen and resident of Orange County, North Carolina.

3. In 2009, Plaintiff's intestate, Juliet J. Jacobs was diagnosed with lung cancer, Stage IV adenocarcinoma with liver and adrenal metastases.

4. In 2010, Juliet J. Jacobs was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy".

5. At the time of her participation in the clinical trials at issue, Juliet J. Jacobs was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

6. At the time of her participation in the clinical trials at issue, Juliet J. Jacobs was informed by Duke University and/or DUHS that she would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Juliet J. Jacobs a higher likelihood of favorable response.

7. At the time of her participation in the clinical trials at issue, Juliet J. Jacobs was informed and believed that her participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Juliet J. Jacobs, with a similar cancer type would normally receive. Juliet J. Jacobs was informed by Duke University and/or DUHS that the cancer clinical trial would offer her cancer a medical treatment that was better than what she would have received without participation in the clinical trial.

8. The chemotherapy that Juliet J. Jacobs paid for and received as a part of the Duke University and/or DUHS clinical trial was not the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for her cancer that had higher likelihood of favorable response, nor was it better than what Juliet J. Jacobs would have received if she had not participated in the clinical trial.

9. The participation of Juliet J. Jacobs was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Juliet J. Jacobs been properly and fully informed, she would have chosen not to participate in the clinical trial.

10. As a result of the conduct of the defendants, Juliet J. Jacobs was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Juliet J. Jacobs was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Juliet J. Jacobs was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

13. That the plaintiff, Walter Jacobs, as Executor of the Estate of Juliet J. Jacobs, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief - Loss of Consortium.

14. That the plaintiff Walter Jacobs, as Executor of the Estate of Juliet J. Jacobs, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

15. At all times referred to in this complaint, Juliet J. Jacobs and Walter Jacobs were lawfully married as husband and wife and had a marital relationship that included marital services, society, affection, companionship, and sexual relations.

16. The injuries sustained by Juliet J. Jacobs caused a loss or disruption of one or more of the elements of marital consortium listed above, and Walter Jacobs suffered a loss of consortium as a result of the injuries sustained by Juliet J. Jacobs as a proximate result of the acts and omissions of the defendants.

17. Plaintiff Walter Jacobs, individually, hereby claims damages under the 18th Claim for Relief- Loss of Consortium, as set out in the attached complaint.

18. That the plaintiff Walter Jacobs, individually, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

19. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.

EXHIBIT 8
Claim of Plaintiff, Polly Johnson,
as Executor of the Estate of Malcom W. Johnson,
and Plaintiff, Polly Johnson, Individually

1. Plaintiff, Polly Johnson was appointed Executrix of the Estate of Malcom W. Johnson, deceased, by the Clerk of Superior Court in Mecklenburg County, Virginia, and is duly qualified and is now acting as Executrix in this action. Polly Johnson is under no legal disability.

2. Plaintiff Polly Johnson, individually, is a citizen and resident of Mecklenburg County, Virginia.

3. In 2010, Plaintiff's intestate, Malcom W. Johnson, was diagnosed with lung cancer, Stage IV T2AN3M1 adenocarcinoma.

4. In 2010, Malcom W. Johnson, was recruited by Duke to participate, and did participate, in a clinical trial conducted by Duke University Health Systems entitled "Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy".

5. At the time of his participation in the clinical trials at issue, Malcom W. Johnson was led to believe that the clinical trials were based on valid, non-falsified research conducted by researchers whose credentials had been verified by Duke University and/or DUHS.

6. At the time of his participation in the clinical trials at issue, Malcom W. Johnson was informed by Duke University and/or DUHS that he would receive genomic-guided chemotherapy that could reliably predict which of two regimens would give Malcom W. Johnson a higher likelihood of favorable response.

7. At the time of his participation in the clinical trials at issue, Malcom W. Johnson was informed and believed that his participation would result in information of benefit to the greater public, a "greater good" and would be better than the standard chemotherapy and treatment that a patient, such as Malcom W. Johnson, with a similar cancer type would normally receive. Malcom W. Johnson was informed by Duke University and/or DUHS that the cancer clinical trial would offer his cancer a medical treatment that was better than what he would have received without participation in the clinical trial.

8. The chemotherapy that Malcom W. Johnson paid for and received as a part of the Duke University and/or DUHS clinical trial was not the standard of medical care, nor the "best" chemotherapy treatment as supplied by a genomic test, nor was it chemotherapy treatment for his cancer that had higher likelihood of favorable response, nor was it better than what Malcom W. Johnson would have received if he had not participated in the clinical trial.

9. The participation of Malcom W. Johnson was fraudulently induced by defendants, as more specifically and fully outlined in the complaint, and had Malcom W. Johnson been properly and fully informed, he would have chosen not to participate in the clinical trial.

10. As a result of the conduct of the defendants, Malcom W. Johnson was deprived of the right to select a physician who was not controlled or influenced by defendant Duke University and/or DUHS and who was not subject to an agenda controlled by the clinical trial as opposed to the best interest of the patient.

11. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Malcom W. Johnson was mentally and physically injured and damaged as a result of the fraudulent inducement by the defendants to participate in the above-referenced clinical trial, which injuries and damages were reasonably foreseeable to the defendants.

12. As a direct and proximate result of the acts and omissions of the defendants as alleged in the complaint, Malcom W. Johnson was mentally and physically injured and damaged as a result of the negligence of the defendants, which injuries and damages were reasonably foreseeable to the defendants.

13. That the plaintiff Polly Johnson, as Executor of the Estate of Malcom W. Johnson, hereby claims damages under all Claims for Relief as set out in the attached complaint except for the 18th Claim for Relief - Loss of Consortium.

14. That the plaintiff Polly Johnson, as Executor of the Estate of Malcom W. Johnson, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

15. At all times referred to in this complaint, Malcom W. Johnson and Polly Johnson were lawfully married as husband and wife and had a marital relationship that included marital services, society, affection, companionship, and sexual relations.

16. The injuries sustained by Malcom W. Johnson caused a loss or disruption of one or more of the elements of marital consortium listed above, and Polly Johnson suffered a loss of consortium as a result of the injuries sustained by Malcom W. Johnson as a proximate result of the acts and omissions of the defendants.

17. Plaintiff Polly Johnson, individually, hereby claims damages under the 18th Claim for Relief- Loss of Consortium, as set out in the attached complaint.

18. That the plaintiff Polly Johnson, individually, shall have and recover of the Defendants a sum in excess of $10,000.00 in compensatory and punitive damages, costs, pre- and post-judgment interest, and all other appropriate relief available in the foregoing causes of action.

19. All allegations and claims set out herein are by reference incorporated and made a part of the attached complaint and all allegations and claims set out in the complaint are by reference incorporated herein and made a part hereof.