IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS, URBANA DIVISION

M. SUZANNE STRATTON, PH.D.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
	)	
THE CARLE CLINIC ASSOCIATION,	)	
	)	
JAMES LEONARD, M.D.,	)	
Chief Executive Officer	)	
Carle Foundation Hospital	)	**JURY DEMAND**
	)	
BRUCE WELLMAN, M.D.	)	**Civil Action No. _____**
Chief Executive Officer	)	
Carle Clinic Association	)	
	)	
and	)	
	)	
KENDRITH ROWLAND, M.D.	)	
Cancer Center Program Director	)	
Carle Clinic Association	)	
	)	
Defendants.	)	
	)	

CIVIL COMPLAINT FOR MONETARY RELIEF AND JURY DEMAND

PRELIMINARY STATEMENT AND INTRODUCTION

1. This is a civil action against Dr. James Leonard, the Chief Executive Officer of the Carle Foundation Hospital ("the Hospital"); the Carle Clinic Association ("the Clinic"); Dr. Bruce Wellman, the Chief Executive Officer of the Clinic; and Dr. Kendrith Rowland, Program Director, Carle Clinic Cancer Center ("the Defendants") for monetary relief for injuries Plaintiff M. Suzanne Stratton, Ph.D. sustained as a result of the Defendants' retaliatory harassment and termination of her employment. The Defendants took these actions in retaliation for Dr. Stratton's whistleblowing about the Hospital and Clinic's failure to comply with federal human

research subject protection regulations during experimental medical trials performed on Clinic cancer patients.

2. Plaintiff, who served as Vice President for Research at the Hospital, investigated, attempted to stop, and reported both internally and to the United States Department of Health and Human Services' National Cancer Institute ("NCI") concerns that the Clinic conducted medical experiments on Clinic cancer patients which violated federal human research subject protection laws, and as a result put patients at risk of harm. She complained repeatedly to Dr. Leonard, Dr. Wellman, Dr. Rowland (who ran many of the trials) and NCI that the Hospital's Institutional Review Board was not correctly reviewing the Clinic studies, despite the fact that it was mandated by federal law to review and approve the Clinic trials for conformance with the federal human subject protection regulations. Dr. Stratton's concerns were dismissed by Hospital administrators, including a Cancer Clinic Director who callously asserted that failure to follow the regulations was of no consequence because the cancer patients were "going to die anyway." Ultimately, Dr. Stratton urged that the Clinic "close accrual" of its trials (i.e., stop accepting new patients on research trials) and formally self-report the noncompliance to OHRP and the FDA. She also advised Hospital and Clinic officials that the Hospital would need to conduct a comprehensive audit into the files of Clinic patients enrolled in trials she knew had violated federal regulations and experimental protocols in order to determine whether patients had been harmed.

3. In retaliation for these and other protected disclosures about the Clinic's violation of the Stark Statute and HIPAA, and within hours of informing Hospital CEO Dr. Leonard of her planned audit of Clinic patient medical records, Dr. Leonard terminated her employment. He did so at the behest of Clinic officials and with the collusion of Drs. Wellman and Rowland who

actively demanded Dr. Stratton's removal. Immediately following Dr. Stratton's termination, Dr. Leonard cancelled the patient medical record audit and took no steps to either stop the accrual of its trials or report the Hospital and Clinic's violations to federal regulators until the federal regulators initiated an investigation into the matter.

4. After Dr. Stratton's termination, NCI and OHRP launched their own investigations into the Clinic's trials. NCI and OHRP documented numerous violations of federal law committed by the Clinic and the Hospital, and corroborated the matters about which Dr. Stratton had complained. NCI ordered that the Clinic cease accepting new patients into its experimental trials.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over this matter pursuant to 28 U.S.C. §1332(a) and (a)(1). The matter in controversy exceeds $75,000 in value and is between citizens of different states.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a)(1) and (2). Defendants engage in business activities within the judicial district of this court and the claims giving rise to this proceeding occurred within the judicial district of this Court.

PARTIES

7. Dr. M. Suzanne Stratton is a citizen of Arizona. For the period of October 2006 up until her termination on November 18, 2008, Dr. Stratton was an employee of the Hospital, which is an "employer" under the Illinois Whistleblower Protection Act, 740 Ill. Comp. Stat. § 174/5.

8. The Clinic is an Illinois corporation with its principal place of business at 602 West University Avenue, Urbana, IL 61801.

9. Dr. James Leonard is a citizen of the State of Illinois. At all times relevant to this Complaint, Dr. Leonard served as Hospital CEO and acted as Plaintiff's supervisor. Dr. Leonard acted within the scope his authority express or implied on behalf of the Hospital in terminating Dr. Stratton and is an "employer" within the meaning of the Illinois Whistleblower Protection Act, 740 Ill. Comp. Stat. § 174/5.

10. Dr. Bruce Wellman is a citizen of the State of Illinois. At all times relevant to this Complaint, Dr. Wellman served as the Executive Officer of the Clinic.

11. Dr. Kendrith Rowland is a citizen of Illinois. At all times relevant to this Complaint, Dr. Rowland served as the Program Director of the Clinic's Cancer Center.

FACTUAL ALLEGATIONS

12. Dr. Stratton has a distinguished record as a cancer researcher and research administrator, with extensive clinical experience running cancer trials and ensuring their compliance with human subject research protection laws. Before beginning graduate school, she spent several years administering new drug trials for private pharmaceutical companies. She received her Ph.D. in Cancer Biology from the University of Arizona in 2001. From 2001 through 2006, Dr. Stratton served as the Director and Principal Investigator in the Prostate Cancer Prevention Program at the University of Arizona's Cancer Center, where she received and administered millions of dollars in federal grants and gained extensive experience in managing clinical trials on human subjects. During this time, she spent several years as a member of the university's Institutional Review Board. Dr. Stratton has developed a deep knowledge of the federal regulatory requirements pertaining to Institutional Review Boards, human subject clinical trials, and the care and treatment of cancer patients.

13. In late 2006, Dr. Stratton began working as Director of Research at the Hospital and was promoted to Vice President for Research in 2007. She reported directly to the Hospital CEO, Dr. Leonard. The Hospital recruited Dr. Stratton to this position to build and administer a multidisciplinary research program, which included human subject trials.

14. Dr. Stratton's job duties included administrative oversight of the Hospitals human subject research activities, which must comply with federal human research subject protections under 45 C.F.R. Part 46 (Department of Health and Human Services regulations on protection of human subjects, which apply in general to institutes receiving federal funding); and 21 C.F.R. Parts 50 and 56 (Federal Food and Drug Administration regulations on protection of human subjects, which apply in addition to the HHS regulations to trials of FDA-regulated drugs and devices).

15. The federal regulations establish an extensive set of obligations intended to protect human subjects, guided by two central standards: ensuring the patients' informed consent, and maintaining a proper balance of risks and benefits to patients. For private institutions such as the Hospital and Clinic, the regulations mandate the creation of private Institutional Review Boards to review proposed experiments ("protocols") and monitor ongoing compliance. 45 C.F.R. Part 46. Institutions conducting covered human subject research must provide an "assurance" to the funding agency that they will submit all experimental protocols to a designated Institutional Review Board for initial approval and seek that Institutional Review Board's prior approval for any changes to its approved protocols. 45 C.F.R. § 46.103(b)(4). Under this "assurance," the institution must also pledge that it will report to the designated Institutional Review Board any serious noncompliance with the regulations, as well as all "unanticipated problems involving risks to subjects." § 46.103(b)(5). The Institutional Review

Board, in turn, must report these events to the funding agency. *Id.* The institution's Institutional Review Board need not be a part of the institution itself, but may be provided by a third party.

16. As per these regulations, the Clinic obtained a "Federalwide Assurance" ("FWA") which designated the Hospital's Institutional Review Board as its Institutional Review Board. During Dr. Stratton's tenure, the Clinic had many hundreds of protocols under the Hospital Institutional Review Board's jurisdiction, including hundreds of protocols being investigated by the Clinic's Cancer Center, run by Dr. Kendrith Rowland, the principal investigator of these experiments. Under these protocols, the Clinic conducted medical experiments on thousands of patients. As signatory on the FWA, Dr. Leonard had legal responsibility for all research conducted under the auspices of the Hospital's Institutional Review Board.

17. Sometime after Dr. Stratton began working at the Hospital, she began to discover serious procedural and substantive deficiencies in Dr. Rowland's trials at the Cancer Center, stemming from lack of proper oversight by the Hospital Institutional Review Board and Dr. Rowland; and the Clinic's flagrant disregard for the Institutional Review Board and federal regulations. She came to believe that this conduct not only violated federal regulations, but also posed serious risk of harm to cancer patients. Dr. Stratton made her views emphatically known to Drs. Leonard, Wellman, Rowland, and many others at the Hospital and Clinic through voluminous emails and public and private discussions. She also directed her staff to assist her in bringing the Institutional Review Board and the Clinic into compliance.

18. When Dr. Stratton arrived at the Hospital, she inherited a very weak Institutional Review Board which was essentially controlled by Dr. Rowland. Rather than subjecting his protocols to the rigorous review required by the regulations, the Institutional Review Board served as a rubber stamp. Dr. Stratton began to take measures to strengthen the Institutional

Review Board and bring it into compliance. She did not learn the full extent of the deficiencies until the fall of 2008, when she began to witness Dr. Rowland's resistance and outright hostility to stronger Institutional Review Board oversight and compliance with the regulations. For its part, the newly empowered Institutional Review Board's more rigorous review process, which Dr. Stratton had insisted be put into place, had begun to identify alarming problems in the Clinic's method of administering the trials, leading to possible harm to patients and noncompliance with regulations.

19. Dr. Stratton's concern about the Institutional Review Board and the Clinic's administration of trials focused on several areas. First, she believed that Dr. Rowland and the Clinic were consistently attempting to interfere with the Hospital Institutional Review Board's independence, in violation of 45 C.F.R. § 46.107(e), in order to prevent his protocols from being subjected to the full initial and ongoing review required by the regulations. Second, she believed that Dr. Rowland was concealing information from the Institutional Review Board about adverse events and mistakes (or "major deviations") made during the conduct of the trials, and preventing the Institutional Review Board from reporting these and other events to HHS and the FDA, in violation of 45 C.F.R. § 46.103(b)(5) and 21 C.F.R. § 56.113. Third, and most seriously, Dr. Stratton came to believe that careless conduct of the Clinic's experiments, removed from proper Institutional Review Board oversight, constituted a systemic and unwarranted risk to patient safety and wellbeing, in violation of the basic purpose of the regulations to protect human subject safety. 45 C.F.R. § 46.111(a)(1) and (2).

20. On or around September 17, 2008, Dr. Stratton met with Dr. Rowland regarding several matters pertaining to the Institutional Review Board, including FDA regulations requiring that the researchers properly report serious adverse events ("SAE"). 21 C.F.R. §§

56.113, 56.108. On September 18, 2008, Dr. Stratton followed up on the meeting by emailing Dr. Rowland, copied to Dr. Leonard, Clinic Chief Administrative Officer Michael Bukosky, and Clinic oncologists Dr. Patricia Johnson, Dr. James Egner, and Ginny Clark, stating:

> I know the IRB reporting may seem arduous and excessive. But I do want to assure you that it is no more than is required by federal regulations . . . Previous policies at Carle lacked the required rigor that is necessary and we are now in compliance. Previously, you forwarded SAE reports to the IRB but they were not associated with a specific study. With that arrangement, our IRB could not adequately track SAEs in a manner required by the FDA.

21. Dr. Rowland grew enraged after receiving Dr. Stratton's email. He came directly to her office and yelled at her for raising these issues. He disparaged her capabilities and insisted that she did not know what she was doing and that "everything was okay before" she came to the Hospital. He made clear that he would continue to resist Dr. Stratton's measures to ensure that these events were reported properly to the Institutional Review Board so that it could track which event had occurred in which study. He told her angrily, "You don't know what you're doing and you will fail at everything you do in your life." During the course of this tirade, Dr. Rowland threatened Dr. Stratton that he was "going to call [her] boss right now." Making good on this threat, he went directly into Dr. Leonard's office to complain about Dr. Stratton and her efforts to bring the Clinic into regulatory compliance. Dr. Leonard then came to Dr. Stratton's office and shrugged his shoulders, acknowledging that Dr. Rowland was acting out of control as he was known to do but rationalized that "it was just the way Ken acts."

22. On October 7, 2008, Dr. Stratton learned from her direct report, Carla Barnwell, then the Interim Director of the Human Subjects Protection Program, that one of Dr. Rowland's Clinic cancer trials had been running without Institutional Review Board approval since December 2007, in violation of federal regulations. Soon thereafter, the Institutional Review Board instructed the Clinic to halt the trial immediately. In response, Dr. Rowland complained

to Dr. Wellman and Dr. Leonard about how "unreasonable" Dr. Stratton was being, maligned her, and objected to her efforts to ensure adherence with legal requirements.

23. By mid-October 2008, Dr. Rowland's overt hostility towards Dr. Stratton and his refusal to follow the law had grown to the point that Dr. Stratton felt obligated to detail her concerns in writing to Dr. Leonard. On October 10, 2008, she emailed Dr. Leonard stating:

> [Rowland] is being antagonistic to IRB staff. He doesn't realize how bad that is . . . Someone has to get a leash on him or there could be serious trouble. Should you or I talk to Bruce [Wellman, CEO of the Clinic]? Ken really shouldn't be the CCOP PI [principal investigator] if he doesn't understand what an IRB does and can't work with one. My thought about talking to Bruce is because I am really concerned about both institutions.

Dr. Leonard failed to respond to this email. However, during a meeting in which Dr. Stratton again raised these concerns, Dr. Leonard merely stated "this is just the way that Bruce wants to do it."

24. Dr. Stratton also began to document and to report other violations at the Cancer Center and the Clinic. On October 10, 2008, she emailed Dr. Leonard about widely distributed Clinic emails containing full patient names and medical details in violation of the Health Insurance Portability and Accountability Act ("HIPAA"). Dr. Stratton wrote that "This is another type of blatant compliance violations there are at the cancer center." Dr. Leonard did not respond.

25. On October 13, 2008, Dr. Stratton met with Clinic Chief Administrative Officer Michael Bukosky, Hospital and Clinic Vice President Richard Brown, Dr. Rowland, and Dr. Johnson to discuss the regulatory compliance issues. Rather than listening to Dr. Stratton's concerns, Dr. Rowland complained about the forms he had to fill out and the time it took for the Institutional Review Board to approve his protocols. During the course of this meeting, Dr.

Rowland insisted that the Institutional Review Board change its procedures. Following this meeting, Dr. Stratton emailed Dr. Leonard about her concerns that the Clinic was attempting to manipulate the Institutional Review Board, in contravention to the required independence mandated by 45 C.F.R. § 46.107(e). Dr. Stratton stated:

> I think [the Hospital] will have a huge risk in continuing to review the cancer center protocols . . . I don't feel good about telling a regulatory body that we allowed investigators to set policy for IRB . . . No investigator should be able to threaten an IRB. I'm completely horrified by that notion and I can't believe it would even be brought up by an investigator . . . This needs fast attention at a high level.

Again, Dr. Leonard ignored Dr. Stratton's concerns and failed to respond to her email.

26. On or around October 14, 2008, Dr. Stratton learned that two groups, the North Central Cancer Treatment Group ("NCCTG") and the Gynecological Oncology Group ("GOG"), had months earlier issued highly critical audits of Dr. Rowland's clinical trials at the Clinic's Cancer Center, but that Dr. Rowland, Dr. Wellman, and the Clinic had concealed these results from Dr. Stratton and the Institutional Review Board. The GOG had audited the Clinic in April 2008, and the NCCTG had audited in July 2008.

27. The NCCTG and GOG are private collectives of regional medical facilities which band together with the support of the National Cancer Institute (NCI) to create experimental protocols for use on-site at their individual facilities. These groups, known as Community Clinical Oncology Programs ("CCOP"), periodically audit their members such as the Clinic in order to assess the scientific integrity of their research. At the same time, the Clinic was subject to its own Institutional Review Board oversight of the same studies. NCCTG and GOG audit findings could include information relevant to patient safety and human subject protection violations.

28. Dr. Rowland, Dr. Wellman, and the Clinic's concealment of the GOG and NCCTG audit results from the Institutional Review Board violated their obligations to facilitate ongoing Institutional Review Board review of active protocols and to notify the Institutional Review Board of any serious noncompliance, deviations from the protocol, or adverse events so that the Institutional Review Board can perform its review and, as appropriate, notify the agency and stop the experiment. 45 C.F.R. §§ 46.103(b)(4) and (5); 46.108.

29. Dr. Stratton turned her attention first to the GOG audit, which had uncovered several alarming deficiencies in the conduct of Clinic studies with implications for patient safety or wellbeing. The GOG audit revealed that a patient had received an inappropriate dose of an experimental regimen of the chemotherapy drug Carboplatin. Dr. Stratton discovered that Dr. Rowland had written a letter to the GOG aggressively rejecting the audit finding that this constituted an unacceptable, major deviation from the study, and had refused to take corrective action.

30. On October 14, 2008, Dr. Stratton forwarded to Dr. Leonard the letter Dr. Rowland had written to the GOG refusing to take corrective action, commenting that "The issue with the [Carboplatin] dose could be a patient treatment issue [i.e., a medical error causing harm to the patient]. He is basically saying that he won't agree it's a deviation because that's the way they have always done it. Not good." Dr. Stratton's office informed the Institutional Review Board of the GOG audit, which in turn reviewed the matter for itself and required Dr. Rowland to explain the negative audit findings and formulate corrective action.

31. Faced with the intense resistance from the Clinic and the highly critical GOG audit, Dr. Stratton grew increasingly convinced that the Clinic's systematic noncompliance could

soon result in patient harm, if it had not done so already. She decided to seek guidance from NCI's Community Oncology and Preventive Trials Research Group.

32. On October 24, 2008, Dr. Stratton sent an email to Dr. Howard Parnes, a Program Director at NCI, asking him for assistance in "reinforce[ing] that IRB review, SAE [serious adverse event] reporting, etc, are necessary . . . I've never seen investigators be so antagonistic." Dr. Parnes put Dr. Stratton in touch with Dr. Lori Minasian at the NCI's Community Oncology and Preventive Trials Research Group.

33. On or around October 24, 2008, Dr. Stratton informed Dr. Leonard that she would be contacting Dr. Minasian at NCI to discuss her concerns.

34. Subsequently, Dr. Stratton disclosed of her concerns about noncompliance to Dr. Minasian and Dr. Parnes, including the negative audit results, the inappropriate pressure by Dr. Rowland on the Institutional Review Board, the resistance to allowing the Institutional Review Board to properly review any protocol deviations – all of which she told Dr. Minasian and Dr. Parnes led her to fear for the safety of patients enrolled in the trials. On the basis of her conversations with Drs. Minasian and Parnes, Dr. Stratton became convinced that the Cancer Center should "close accrual" of its trials (i.e., stop accepting new patients on research trials) and formally self-report the noncompliance to the Department of Health and Human Service's Office of Human Research Protections ("OHRP"), as required by 45 C.F.R. §§ 46.103(b)(5); 46.108.

35. Dr. Stratton informed Dr. Leonard about her conversation with Dr. Minasian. Despite the seriousness of this issue, Dr. Leonard failed to provide any meaningful response, and instead remarked "I don't know what to tell you."

36. On October 25, 2008, Dr. Stratton emailed Dr. Leonard to discuss her rising frustration with her attempts to ensure regulatory compliance at the Clinic and Hospital. Dr.

Stratton wrote that although the situation was frustrating her, she had no intention of leaving the Hospital: "I made a long-term commitment to Carle and your vision. I remain committed to making it work. I've had a chance to talk to colleagues [Dr. Minasian and Dr. Parnes at NCI] and I have renewed confidence on the direction we are going."

37. At around this time, Dr. Stratton realized that Dr. Rowland was attempting to induce the Hospital to violate the Stark Statute, 42 U.S.C. § 1395nn, which prohibits federally funded physicians from benefitting from self-referrals. Dr. Rowland had been pushing for Hospital staff to provide free services to the Clinic to assist the Clinic in complying with its Institutional Review Board obligations. On October 28, 2008, Dr. Stratton emailed Dr. Leonard that "That obviously would be a Stark violation." Dr. Leonard again failed to respond or take any form of corrective action.

38. On October 28, 2008, Dr. Stratton again emailed Dr. Leonard with her concerns. She forwarded him an email from her staff member, Ms. Barnwell, stating that "all research is at risk if we are visited [by HHS] over their [the Clinic and Dr. Rowland's] noncompliance." Dr. Stratton wrote Dr. Leonard that in light of this serious noncompliance with federal regulations, "[Dr. Wellman] needs to shut [Dr. Rowland] down or [Dr. Rowland] will bring down the entire Cancer Center . . . I'm going to try to have a fast and peaceful meeting with [Dr. Wellman] next week to get his view on all of this. I would like to share of the facts with him as they relate to regulation. I could even have NCI people come out and talk to him if he wants."

39. On October 29, 2008, Dr. Stratton's staff member Ms. Barnwell emailed the Institutional Review Board Chair, Dr. John Zech, regarding federal requirements under 45 C.F.R. § 46.103 and 21 C.F.R. §§ 56.113, 56.108 that the Institutional Review Board report to the FDA that it had suspended approval Clinic study. Dr. Rowland had strenuously objected to reporting

to the FDA and had attempted to convince Dr. Zech that the report was unnecessary. Dr. Zech wrote pleadingly to Ms. Barnwell and Dr. Stratton that "I have no legal training and perhaps I do not have a full understanding of the regulations. Do we have any experts available to help us be certain that the IRB is following all regulations and meeting all of our responsibilities?"

40. On October 31, 2008, Dr. Stratton again emailed Dr. Leonard to complain about the Clinic's noncompliance with HIPAA privacy regulations, reporting that the Clinic had included full patient names and medical record information in a non-confidential email. Dr. Stratton wrote that "it really has to stop. It's a major violation[] since, as you know, email is not considered confidential unless CFR 21 Part II compliant encryption algorithms are in place." Again, Dr. Leonard failed to respond or take any form of corrective action.

41. Throughout this period, Dr. Stratton began to suffer serious medical problems as a result of the stress and harassment to which she was being subjected. Dr. Stratton kept Dr. Leonard fully advised about the toll to her health Dr. Rowland's abusive treatment had caused her, and the anxiety she was experiencing as a result of the Hospital's and the Clinic's refusal to adhere to federal regulations and protocols concerning the Clinic's medical experimentation on human subjects.

42. In early November 2008, Dr. Stratton began reviewing the NCCTG audit, which, in addition to the GOG audit, suggested the existence of serious compliance and patient safety problems at the Clinic and Hospital. Dr. Stratton stayed in contact with Dr. Minasian at NCI and emailed her about the GOG and Dr. Rowland's refusal to take corrective action. Dr. Stratton also learned from the Institutional Review Board Chair, Dr. Zech, that Dr. Rowland had refused to provide the Institutional Review Board with his full correspondence with the GOG auditors,

again in violation of the Clinic's regulatory obligation of transparency and full reporting to the Institutional Review Board. 45 C.F.R. §§ 46.103(b)(4) and (5).

43. On November 4, 2008, Dr. Stratton informed Dr. Leonard and NCI about her grave concerns surrounding Dr. Rowland and the Clinic's continued attempts to influence Institutional Review Board decisions about studies in which Dr. Rowland was the principal investigator; his refusal to provide documents to the Institutional Review Board; and other violations. In particular, Dr. Stratton reported that Dr. Rowland was now resisting the FDA requirement that any Institutional Review Board suspension of an FDA-regulated study be reported to the FDA as required by 21 C.F.R. § 56.113, which Ms. Barnwell had previously emailed Dr. Zech about as described above in ¶ 39. The Institutional Review Board had suspended several of Dr. Rowland's studies because they had "lapsed"—that is, had not been re-approved by the Institutional Review Board in time as required by the regulations and as such must be suspended by the Institutional Review Board. The Institutional Review Board intended to report the suspensions to the FDA, in a letter drafted by Dr. Stratton to go out under her signature, which angered Dr. Rowland. Rather than deferring to the Institutional Review Board's decision, Dr. Rowland threatened the Institutional Review Board chair Dr. Zech and attempted to convince the Institutional Review Board that he himself (rather than Dr. Stratton) should do the research to decide whether the Institutional Review Board must report his lapsed studies to the FDA. Dr. Stratton was very concerned at Dr. Rowland's attempts to improperly influence Dr. Zech and the IRB, given Dr. Zech's plea for assistance just a week earlier in which he stated that that "I have no legal training and perhaps I do not have a full understanding of the regulations." See *supra* ¶ 39. Dr. Stratton emailed Dr. Minasian at NCI that day to inquire

about the FDA reporting requirements. Despite Dr. Stratton's efforts, the study suspensions were not reported to the FDA as required.

44. That same day, November 4, 2008, Dr. Stratton emailed Dr. Leonard after getting confirmation of her concerns from Dr. Minasian. She stated:

> I can't stress how serious things are over there as far as noncompliance goes. We cannot have the clinic or a single investigator dictate how the IRB runs. This is a complete conflict of interest. Also, Ken [Rowland] is withholding documents from us . . . I don't understand why all of this is okay. IRBs do not have to ask for permission to request information or report an event. I've never seen this type of behavior before . . . I spoke with one of the NCI leaders today and my concerns were well-validated. If the clinic continues to minimize the issues they could get into much more trouble . . . Something extremely significant needs to happen to turn this around. I can't compromise my own ethical and legal obligations to make Ken [Rowland] happy.

Dr. Leonard's only response to Dr. Stratton's concerns was to repeat his oft-stated phrase "I don't know what to tell you" and to emphasize that "this is what Bruce wants." Once again, Dr. Leonard failed to take correct action.

45. Later on the afternoon of November 4, 2008, Dr. Stratton emailed Mr. Brown about the FDA regulations. Mr. Brown, a Vice President with joint appointments at the Clinic and Hospital, had been recently detailed by the Clinic's CEO Dr. Wellman to intervene in the Institutional Review Board compliance matter – despite the fact that he had no understanding of the legal requirements and did not even know what the initials "IRB" (the acronym for "Institutional Review Board") stood for when he first spoke to Dr. Stratton about it. Copying Dr. Leonard on this email, Dr. Stratton emphasized to Mr. Brown that the Clinic needed to comply with the FDA regulations and provided a link to the relevant regulations. However, Mr. Brown never took appropriate corrective action. Instead, whenever she urged him to address the noncompliance and the Clinic's illegal conduct, he responded that all he cared about was that "his doctor" (Dr. Rowland) was upset, and that his job was to make Dr. Rowland happy."

46. On November 5, 2008, Dr. Stratton emailed Dr. Leonard expressing her frustration again at the Cancer Center's willful and rampant regulatory noncompliance. She stated that "the violations we have at the cancer center are things that keep me up at night – they should keep you up too – and Bruce [Wellman] also. But rather than being able to fix anything I get stuck defending FDA regulations which are clearly in writing."

47. Later on the afternoon of November 5, 2008, having received no meaningful response to her clarion call, Dr. Stratton again emailed Dr. Leonard, voicing her sharply mounting concern and her unwillingness to participate in the violation of federal law and regulations. She stated:

> With IRB being ultimately being controlled by one angry investigator who has put his entire institution and your institution at risk, I cannot be comfortable assuring IRB compliance. My values are completely being challenged . . . I can't live with being aware of serious compliance and ethics issues with no hope or support in correcting them . . . This isn't what I want Jim but I can't watch it go down this path . . . I don't know that I can live with the way things are or the way they are going. There are documents we requested weeks ago that we still have not received from Ken and they directly relate to care of a human subject on his trial. The CCOP grant was never reviewed by IRB and that's a federal offense . . . I don't think I can be responsible for IRB compliance at the cancer center anymore.

48. Dr. Leonard responded to Dr. Stratton's email referenced above in ¶ 47 on November 5, 2008, stating that "The problems u have outlined sound huge & I cannot imagine they would be ignored." Although Dr. Leonard acknowledged the magnitude of the problem, he again refused to take any action. In response to Dr. Leonard's continued refusal to confront the issues she had raised, Dr. Stratton replied, "Yes – the problems are huge – you have no idea. And yes – they are being ignored. This is not the way the rest of the world works." Dr. Leonard failed to respond to this email.

49. Increasingly concerned about the Clinic's serious regulatory noncompliance and Dr. Leonard's refusal to take corrective action, Dr. Stratton once again contacted Dr. Minasian at NCI about the audits and reporting requirements. Dr. Minasian confirmed that any "major deviations" (i.e., noncompliance with the regulations) must be reported to the NCI and possibly to the FDA for an FDA-regulated experimental drug. She also wrote that "If there is any evidence of misconduct, then it is the role of the IRB and the PI to suspend new accrual [i.e., enrollment of new patients] until the issue is resolved." Dr. Stratton responded by email to Dr. Minasian dated November 6, 2008, stating that:

> unfortunately things here have become worse and pretty hostile of the past few days . . . Ken [Rowland] and one of the clinic administrators are now looking into 'what the IRB is permitted to do' . . . obviously this is a conflict of interest since the PI is pretty much being allowed to determine how to run the IRB . . . the IRB still cannot get the documents they request, like the response letter from Dr. Blessing [the GOG auditor] . . . the lack of transparency is disconcerting.

50. During the first week of November, 2008, Dr. Stratton raised concerns about the Clinic's failure to follow federal regulations concerning its clinical trials during a meeting with Mr. Brown, Dr. James Egner, the Medical Director for the Hematology/Oncology Department of the Clinic, Melissa Phillips, the Clinic Cancer Center Director, and Dr. Rowland. During the meeting, Ms. Phillips remarked that the protocol deviations were of no consequence given the medical condition of the patients involved in the studies. She stated "what difference does it make if there is a protocol deviation on someone that's going to die anyway?" Ms. Phillips had made a similar comment in the presence of Dr. Stratton's staff member, Anna Keck, during the same time period, and Ms. Keck reported the comment to Dr. Stratton. These comments further contributed to Dr. Stratton's concerns about the Clinic's lack of regard for patient care.

51. Around November 10, 2008, Dr. Stratton spoke with Dr. Malcolm "Mike" Hill, a Clinic doctor who was also a member of the Hospital's Board of Trustees, about the ongoing

problems with the Clinic and the Institutional Review Board. She detailed the issues of non-compliance referenced above. Dr. Hill concurred that the issues Dr. Stratton raised were serious and told Dr. Stratton that he would put the Institutional Review Board on the agenda for the next Hospital Board meeting, to take place at the end of the week. He also indicated that he would talk to Dr. Leonard about the concerns Dr. Stratton had raised concerning the Clinic's non-compliance with federal regulations. Dr. Hill later advised Dr. Stratton that Dr. Leonard responded angrily when he relayed the concerns that Dr. Stratton had brought to his attention.

52. On November 10, 2008, Dr. Stratton emailed Dr. Leonard to inform him that the Institutional Review Board would be discussed at the Hospital Board meeting. She assumed that making the presentation to the Board would naturally fall to her given her expertise about the issues, and she asked Dr. Leonard for guidance. Dr. Leonard responded brusquely that he would make the presentation, which would be only "a brief overview that we will be legal." Dr. Stratton, concerned that Dr. Leonard's presentation to the Board would be too perfunctory, requested that she at least be allowed to attend the Board meeting to be able to field any questions that might arise. Dr. Leonard responded by email dated November 11, 2008 accusing her of engaging in "speculative discussion or a personnel friction discussion – if u can refrain and mike can refrain you can be there – this is non[] negotiable." Dr. Leonard's response indicated his desire to suppress her whistleblowing and to denigrate her concerns as merely "speculative" or related to "personnel friction," rather than to actual noncompliance and threats to patient safety. Indeed, at the Board meeting Dr. Leonard gave a truncated and misleading description of the issue, concealing from the Board the true extent of the noncompliance of the Institutional Review Board and the Clinic.

53. During this period, the Clinic CEO, Dr. Wellman, began blaming Dr. Stratton for creating "personality issues" with respect to the Institutional Review Board and declined to investigate her well-documented concerns about regulatory noncompliance. By email to Dr. Wellman dated November 11, 2008, Dr. Stratton asked to "talk face to face about the IRB . . . The most important thing for me is that we get into full compliance with OHRP, FDA, and NCI regulations and guidance." Dr. Wellman refused to meet with her and responded dismissively that "This issue is very frustrating . . . but in the end I am not going to referee personality issues." Dr. Wellman also indicated that he would no longer be communicating with Dr. Stratton about the issue but instead would have Clinic officers and staff (including Mr. Brown, the Vice President who did not even know what "IRB" stood for) go directly to Dr. Leonard and bypass Dr. Stratton.

54. On November 12, 2008, Dr. Stratton emailed Dr. Leonard regarding yet another Institutional Review Board compliance issue and requested that he take appropriate corrective action. She reported that a Clinic oncologist, Dr. Bharat Gopal, had attempted to evade Hospital Institutional Review Board review of his study altogether and then attempted to pressure the Hospital Institutional Review Board to waive review in deference to another institution's Institutional Review Board. Dr. Stratton emailed Dr. Leonard stating:

> Consider the compliance issues we are having now which are getting larger by the day . . . the short answer? Federal policy would allow the local IRB [i.e., the Hospital Institutional Review Board] to defer. But, if the local IRB would not defer and the investigator goes ahead, he will have a tough time doing research ever again anywhere since it's a federal violation to defy a local IRB . . . I've never seen anyone treat an IRB with outright refusal . . . we are going down a very bad path. Please support me.

Dr. Leonard did not respond to this email or take corrective action.

55. On November 14, 2008, after experiencing much difficulty because of Dr. Rowland's resistance to turning over the records, Dr. Stratton finally received a copy of the finalized NCCTG audit and the Clinic's response. This audit confirmed Dr. Stratton's worst fears about risks to Clinic patients, as it listed twelve "major deviations" from the Institutional Review Board-approved protocol which related directly to patient care issues – such as incorrect dosages given to patients and patients enrolled in the study with potentially harmful contraindications. At this point, Dr. Stratton's concerns began to take on new urgency, as she had assembled a growing body of negative audit findings indicating that the Clinic's noncompliance during the course of its medical experiments on patients was actually threatening patient care and that Dr. Rowland and the Clinic had concealed these findings from the Institutional Review Board. Accordingly, Dr. Stratton began to formulate plans to encourage the Institutional Review Board to investigate whether any patients had actually been injured at the Clinic because of its noncompliance with federal regulations.

56. On November 14, 2008, Dr. Stratton emailed Dr. Leonard, stating:

> I have been sent a few of the audit reports from the cancer center . . . I am seeing a pattern that is of concern. All of the reports I have seen have major deficiencies and many of those deficiencies related to subject care . . . In my career I've never seen some of these deviations before. Some of these could seriously cause harm – for all I know they did. We are going to have to follow up on these patients.

57. At the close of her November 14, 2008, email to Dr. Leonard, Dr. Stratton listed some of the major deviations which most concerned her, taken from the NCCTG audit. These included:

- "Enrolling ineligible patient (patient had Gliodil wafers which were an exclusion criteria)." In this case, a patient had a drug delivery device implanted in his brain, which should have rendered him ineligible for the study, since the experimental medication would cross the blood-brain barrier with no way to predict how it would interact with the brain implant.

- "Dose deviations"; "incorrect calculation of dose"; and "unjustified dose modification." In these cases, patients had mistakenly or deliberately received doses that did not correspond to the Institutional Review Board-approved experimental protocol.

- "Administration of prednisone not permitted in the protocol." This constituted another example of possibly harmful drug interactions between the experimental drug and another drug the patient was taking.

- "Labs drawn one day after chemo rather than before." This meant that the results of required pre-chemotherapy laboratory tests on patients were not available prior to administration of experimental drugs. The pre-chemotherapy tests are required to ensure that parameters such as blood counts, kidney function, and liver function are within the safe limits specified by the experimental protocol or medical best practices. For example, administration of myelosuppressive chemotherapy – which reduces white blood cell count – when white blood counts are already too low can result in fatal consequences such as sepsis or neutropenic fever, a life-threatening condition that requires immediate hospitalization.

- "Lack of follow-up after AE [adverse event]." The Clinic failed to investigate whether an adverse event was related to the experiment, possibly endangering the patient and compromising the experimental data.

58. Also on November 14, 2008, Dr. Stratton discussed the Clinic's noncompliance again in person with Dr. Leonard, stressing that it was illegal for Clinic researchers to interfere with the Institutional Review Board and that she could not oversee the Institutional Review Board under such outright illegality. As he had numerous times before when she raised her concerns, Dr. Leonard brushed her off and replied "that's just what Bruce [Wellman] wants. I don't know what to tell you."

59. After reviewing the full NCCTG audit report, Dr. Stratton determined that she needed to encourage the Hospital Institutional Review Board to audit the Clinic in order to determine whether any patients had been harmed. Dr. Stratton informed Dr. Leonard that she was going to discuss her concerns about harm to patients and the NCCTG audit with Dr. Minasian at NCI. Dr. Stratton emailed Dr. Minasian on November 17, 2008, about the NCCTG audit, stating:

> [M]any of the major deviations may have directly impacted patient care and outcome. Two obvious example include enrolling an ineligible patient (patient had Gliodel wafers . . .). . . and failing to do the pretreatment blood draws.
>
> Clearly, we must quickly follow up on our end to determine whether these subjects were adversely affected by any of these deviations. These are not isolated cases. There are quite a few.
>
> In the big picture, the more I consider our options, the more I realize that we need help from outside . . . My instincts tell me we need to hold new studies and new accrual until everything is straightened out . . .
>
> At what point and to what extent can your office step in? . . . I care about my institution and nothing is more important to me than protecting human subjects. My urgency about this is due to the fact that patient care is affected the deviations are not simple documentation errors.

60. On or around November 17, 2008, Dr. Stratton spoke with the Institutional Review Board Chair, Dr. Zech, about the troubling NCCTG audit findings. Dr. Zech agreed that the Institutional Review Board should conduct its own internal follow-up audit to investigate whether any patient harms had resulted from the deviations identified in the NCCTG audit. Dr. Zech requested Dr. Stratton's assistance in drafting a letter to Dr. Rowland and the Clinic notifying them about audit. Accordingly, Dr. Stratton directed her staff member, Dixie Mayol, to begin the process of following up on patients. The draft letter, dated November 18, 2008, stated that:

> In response to receiving the July 29-30, 2008 NCCTG Audit Report, the IRB has decided to conduct an internal audit of the files with which there were major deficiencies We ask that your office please pull all affected patient and study files by our proposed time – Thursday, November 20th.

61. On the morning of November 18, 2008, Dr. Stratton informed Dr. Leonard about the Institutional Review Board's plans to audit Dr. Rowland and the Clinic and to search for evidence of harm caused to patients by the Clinic's noncompliant and mismanaged experiments. She showed him a draft copy of the letter she had written for Dr. Zech's signature. She informed

Dr. Leonard that she intended to report the NCCTG audit to OHRP. That morning she also emailed Dr. Leonard forwarding him the NCCTG report and informing him of the Institutional Review Board's plans to audit the Clinic. She once again expressed her conviction that the Clinic and the Hospital Institutional Review Board were operating in a manner contrary to federal regulations and recommended that new patient accrual be halted at once. She stated:

> Attached is the audit report to which I was referring. Note that out of 29 cases reviewed there were 12 major deficiencies directly related to patient care.
>
> Dr Zech will be sending a letter to Dr Rowland informing him that IRB staff will be auditing those cases this Thursday and Friday to determine whether any patients were harmed as a result of these major deviations. After that we will have to discuss a long-term plan of education and accountability of investigators
>
> It would be the best approach to close the cancer center to new studies and new accrual until this is straightened out. Subject already enrolled on studies would not be affected. Can you support me on this and talk to Bruce? . . .
>
> I feel completely irresponsible not taking action in a major way but I feel unable to do so. Twelve out of 29 cases having a patient care issue is a terrible statistic. We obviously need to dive deep into this. But to be able to do so, the other reviews will have to stop. Also, with these deviations noted I can't feel right about allowing new studies to open and enrolling more subjects since it seems they cannot handle what they have. Unfortunately, it appears that this is not an unusual audit report which makes me even more concerned. I know I have told you all of this before, but I need to get your view of the situation. How will Bruce respond to this?
>
> I will ask that Dr Zech copy both of you, Bruce and Rich Brown on the letter. It should be going out today.

62. On November 18, 2008, just hours after Dr. Stratton informed Dr. Leonard of her plans to initiate an audit of patient records and report the situation to OHRP, and urged that the Clinic and the Hospital close the Clinic's Cancer Center to new studies and new accrual, Dr. Leonard summarily fired her. He gave her no performance-related reason for her termination, and instead emphasized that she had "done a great job" but that it was time for her to "move on." Dr. Leonard told Dr. Stratton that he had made the decision to terminate her over the weekend. Dr. Stratton, who prior to this point, held Dr. Leonard in the highest esteem, was devastated by

his callous treatment of her, and felt especially betrayed that he had caved to pressure that Drs. Rowland and Wellman had exerted to have her fired. Dr. Stratton tried to remain composed during this meeting, but ultimately broke down in tears and Dr. Leonard then escorted Dr. Stratton to the office of Phil Kubow, Vice President of Human Resources, to discuss the details of her termination. Mr. Kubow then directed her to pick up her purse and leave the building at once. Mr. Kubow declined Dr. Stratton's request to be able to make a few telephone calls prior to leaving.

63. Almost immediately after terminating Dr. Stratton, Dr. Leonard ordered Dixie Mayol, Dr. Stratton's staff member who had been about to transmit the letter announcing the audit to Dr. Rowland, not to send the letter. As a result, the letter was never sent and the audit never took place.

64. Dr. Stratton returned to the Hospital two weeks after her termination to retrieve her personal belongings. The Hospital required that she be supervised by a security guard, which caused her further humiliation and distress.

65. Shortly after Dr. Stratton was terminated, several Hospital and Clinic employees told her that they believed her termination had been in retaliation for her whistleblowing. Others told her that they heard she had quit for "health reasons" – suggesting that the Hospital, Dr. Leonard, and the Clinic were spreading false and defamatory reasons for her departure.

66. Despite the close professional relationship they had shared and Dr. Leonard's awareness that the Hospital's termination of Dr. Stratton would be professionally and personally devastating to her and her health, Dr. Leonard never contacted Dr. Stratton and indeed refused her email request to "talk sometime," responding "I have no interest in having a discussion." This refusal further exacerbated Dr. Stratton's feelings of isolation and depression. However, in

December 2008, Dr. Leonard finally responded to an email in which Dr. Stratton asked what he would tell prospective employers who called him for a reference. By email dated December 12, 2008, Dr. Leonard acknowledged that Dr. Stratton's push for compliance had been the reason for her termination. He stated that he would tell potential employers calling him for job references that:

> You . . . did a good job, there were many unanticipated infrastructure deficiencies that needed to be fixed, and as those changes were made the cultural resistance to change built to the point where it was difficult to move things ahead and I decided a fresh set of eyes was necessary.

67. As this email clearly demonstrates, "cultural resistance" – i.e., Dr. Rowland and the Clinic's refusal to come into compliance and resulting anger at Dr. Stratton for insisting on compliance – led to Dr. Leonard's decision to terminate her. Indeed, nothing in Dr. Stratton's job performance would have caused her termination. Iin October 2008, just weeks before her termination, Dr. Leonard gave Dr. Stratton a raise from $164,000 to $171,000, plus a 15% discretionary, merit-based bonus – the highest level merit bonus given out to Hospital executives. In addition, Dr. Leonard gave Dr. Stratton a deferred $10,000 "incentive to stay" bonus in October 2008, which would have vested if Dr. Stratton stayed at the Hospital for an additional five years. Her last performance review conducted by Dr. Leonard in June 27, 2008, was laudatory and closed with "I am glad that Dr. Stratton is here. She is doing an excellent job and I look forward to her excited contributions during the next year."

68. Shortly after Dr. Stratton's termination, OHRP and NCI began to investigate the Clinic and the Hospital to determine its compliance with federal human subject protection regulations. The compliance investigation, which is still ongoing, included a three-day on-site evaluation of the Hospital and Foundation by the federal agencies, interviews with Hospital and Clinic employees, and an examination of the Hospital and Clinic's records. The investigation

has substantiated Dr. Stratton's concerns: On June 9, 2009, and September 21, 2009, OHRP issued letters ("the Determination Letters") finding that the Clinic and the Hospital were seriously out of compliance with the human subject protection regulations mandated by 45 C.F.R Part 46, just as Dr. Stratton had said. On June 11, 2009, NCI wrote to the Clinic referencing OHRP's finding of noncompliance and ordered that all of the Clinic's studies be closed to new patient accrual, which Dr. Stratton had also urged.

69. Both OHRP Determination Letters substantiated Dr. Stratton's concerns that the Clinic's Cancer Clinic experiments, as reviewed by the Hospital IRB, were generally out of compliance with federal regulations. The June 9, 2009 OHRP Determination Letter stated OHPR's concern that the Hospital IRB had, as a matter of general practice, failed to subject the Cancer Center studies to the human subject protections review mandated by the regulations, and had instead applied a lenient, noncompliant standard of review – in contrast to the more rigorous review applied to of non-Cancer Center studies. This corroborates Dr. Stratton's repeated complaints that Dr. Rowland was allowed to dominate the Institutional Review Board and appeared to expect and receive special treatment from it. Likewise, the September 21, 2009 Determination Letter found that Dr. Leonard had "failed to fulfill the obligations imposed by HHS regulations for the protection of human subjects."

70. The OHRP Determination Letters substantiate Dr. Stratton's specific concerns in addition to her global concerns about noncompliance. For example, both Determination Letters found that the Clinic and Hospital Institutional Review Board had failed to comply with its reporting requirements mandated by 45 C.F.R. 46.103(a) and 103(b)(5) pertaining to the NCCTG audit findings and possible patient care issues. The June 9, 2009 Determination Letter found that the Clinic had unlawfully withheld documents from the Hospital Institutional Review Board, in

violation of 45 C.F.R § 103(b)(4) and (5) rather than automatically providing them to the IRB, just as Dr. Stratton had complained. The June 9, 2009 Determination letter noted that it obtained documentation indicating that Dr. Leonard and the Clinic had been aware of "an investigator's interference with both the Carle Foundation and Carle Clinic's responsibility to report, in a timely fashion, unanticipated problems involving risks to subjects and others and continuing noncompliance with 45 CFR Part 46 to OHRP." Although made anonymous, the "investigator" referred to here is on information and belief Dr. Rowland, about whose improper interference with the Institutional Review Board Dr. Stratton had strenuously complained to Dr. Leonard.

71. The OHRP Determination Letters substantiated Dr. Stratton's account of the events leading up to her retaliatory termination directly after she attempted to convene the internal audit of the NCCTG findings. Both Determination Letters note the allegation that Dr. Stratton had been fired after she had "made attempts to bring the research at your institutions into compliance with HHS regulations at 45 CFR Part 46." Both Determination Letters then stated that OHRP had "received documentation" about the following facts:

- The NCCTG audit findings revealed "unanticipated problems involving risks to subjects and others and continuing noncompliance";
- Dr. Stratton had been terminated on November 18, 2008 very shortly after she informed Dr. Leonard of the scheduled internal audit of the patient files involved in the NCCTG audit findings; and
- The internal audit of the Clinic Dr. Stratton planned to look into these very serious concerns was never completed, and no action was taken by the IRB on the NCCTG findings until *after* the Hospital and Clinic received inquiry letters from OHRP.

The September 21, 2009 Determination Letter concluded its discussion of these and other facts surrounding Dr. Stratton's termination by stating that "Given the above, we determine that [Dr. Leonard] and the prior Carle Clinic Signatory Official failed to fulfill the obligations imposed by the HHS regulations for the protection of human subjects."

72. The September 21, 2009 Determination Letter states that Dr. Leonard told OHRP that the reason he stopped the Clinic audit Dr. Stratton had planned just before her termination was that "he determined that prior to an internal audit . . . it would be beneficial to meet with Carle Clinic executives to discuss the issues raised in the NCCTG audit report."

73. As a direct result of Dr. Leonard, Dr. Rowland, Dr. Wellman, and the Clinic's actions, Dr. Stratton has suffered serious financial, emotional, and physical harms. She was placed on anti-depressant medication. Following her termination, she became severely depressed. The stress and depression caused by Defendants' mistreatment of her also exacerbated her physical condition, including high blood pressure, peripheral arterial disease, and an aneurism. As a direct result of Dr. Leonard's termination of Dr. Stratton's employment, she became ineligible for the disability insurance to which she was covered during the period of her employment.

74. Upon information and belief, Dr. Leonard has engaged in a pattern and practice of retaliating against Hospital and Clinic employees who have reported concerns about patient care at the Hospital and at the Clinic.

COUNT I: WRONGFUL TERMINATION AGAINST DR. LEONARD IN VIOLATION OF THE ILLINOIS WHISTLEBLOWER ACT

75. Plaintiff incorporates as though restated each of the allegations set forth in paragraphs 1-74 above.

76. Dr. Stratton repeatedly communicated and attempted to communicate to the FDA, NCI, and OHRP her reasonable belief that the Clinic trials, as overseen by the Hospital Institutional Review Board, violated federal human research subject protection regulations. She reported her concerns to Dr. Minasian and Dr. Parnes at NCI, and detailed Dr. Rowland's interference with the Hospital Institutional Review Board's independence, in violation of 45 C.F.R. § 46.107(e); Dr. Rowland's concealing and failing to report information to the Institutional Review Board, thereby preventing reporting to the FDA and OHRP, in violation of 45 C.F.R. § 46.103(b)(5) and 21 C.F.R. § 56.113; and the Clinic and Hospital's creation of risks to patient safety in violation of the basic purpose of the regulations to protect human subject safety under 45 C.F.R. § 46.111(a)(1) and (2). At the time of her termination, Dr. Stratton was also attempting to ensure that the Hospital Institutional Review Board report the Clinic's failure to secure continued Institutional Review Board approval of trials to the FDA or OHRP, as required by law, and that the Institutional Review Board properly audit the Clinic's files and report any further violations to the FDA and/or OHRP.

77. Dr. Stratton informed Dr. Leonard about her complaints to Dr. Minasian at NCI, her efforts to ensure proper Institutional Review Board reporting of violations to the FDA and HHS, and her intentions to audit the Clinic files, which would have lead to additional reports of violations to the Institutional Review Board, the FDA, and OHRP.

78. In retaliation for Dr. Stratton's complaints, and to prevent further reports to the FDA and/or OHRP, Dr. Leonard terminated her employment just hours before she was to send a letter to Dr. Leonard and the Clinic announcing the Institutional Review Board's plan to conduct an audit of the Clinic's files and patient records.

79. Dr. Leonard's actions violated the Illinois Whistleblower Protection Act, which forbids retaliation against any employee "for disclosing information to a government or law enforcement agency, where the employee has reasonable cause to believe that the information discloses a violation of . . . federal law, rule, or regulation." 740 Ill. Comp. Stat. 174/15.

80. As a direct and proximate result of the foregoing, Dr. Stratton has lost the benefits and privileges of employment, and has suffered additional economic and non-economic damages including the loss of salary, perquisites and employment benefits, emotional distress, emotional anguish, physical injury, and irreparable, continuing to harm her career.

WHEREFORE, Dr. Stratton respectfully requests that this Court enter judgment in her favor and against defendant Dr. Leonard, and provide the following relief:

(a) Award Dr. Stratton damages sufficient to compensate her for all lost wages and benefits she has and will continue to incur in an amount to be proved at trial;

(b) Enter an order reinstating Dr. Stratton to her former position;

(c) In the alternative, award Dr. Stratton damages for front pay and benefits in an amount to be proved at trial;

(d) Award Dr. Stratton her costs and reasonable attorney fees;

(e) Award such other relief as the Court deems to be just.

COUNT II: CIVIL CONSPIRACY AGAINST DR. LEONARD, DR. WELLMAN, DR. ROWLAND AND THE CLINIC TO VIOLATE THE ILLINOIS WHISTEBLOWER PROTECTION ACT

81. Plaintiff incorporates as though restated each of the allegations set forth in paragraphs 1 through 80 above.

82. Dr. Stratton repeatedly reported and/or attempted to report to the NCI, the FDA and OHRP her reasonable belief that the Clinic trials, as overseen by the Hospital Institutional Review Board, violated federal human research subject protection regulations. She reported her concerns to Dr. Minasian and Dr. Parnes at NCI about Dr. Rowland's interference with the Hospital Institutional Review Board's independence, in violation of 45 C.F.R. § 46.107(e); Dr. Rowland's concealing and failing to report information to the Institutional Review Board, thereby preventing reporting to OHRP and the FDA, in violation of 45 C.F.R. § 46.103(b)(5) and 21 C.F.R. § 56.113; and the Clinic and Hospital Institutional Review Board's creation of risks to patient safety in violation of the basic purpose of the regulations to protect human subject safety under 45 C.F.R. § 46.111(a)(1) and (2). At the time of her termination, Dr. Stratton was also attempting to ensure that the Hospital Institutional Review Board report the Clinic's failure to secure continued Institutional Review Board approval of trials to the FDA or OHRP, as required by law, and that the Institutional Review Board properly audit the Clinic's files and report any further violations to the FDA and/or OHRP.

83. Dr. Stratton informed Dr. Leonard about her complaints to NCI, her efforts to ensure proper Institutional Review Board reporting of violations of the human research subject protection regulations to the FDA and OHRP, and her intentions to audit the Clinic files, which would have led to additional reports of violations to the Institutional Review Board, the FDA, the NCI, and OHRP. Dr. Stratton also informed the Clinic, Dr. Wellman, and Dr. Rowland about her efforts to ensure proper Hospital Institutional Review Board reporting of violations of the human research subject protection violations to the FDA and/or OHRP.

84. Dr. Leonard agreed with Dr. Rowland, Dr. Wellman, and the Clinic to retaliate against Dr. Stratton for her whistleblowing and prevent her from auditing the Clinic's files,

which would have lead to further reports of violations to the FDA, NCI, and/or OHRP. Evidence of this agreement includes Dr. Leonard's admission to OHRP that he stopped Dr. Stratton's audit because he intended to meet with Clinic executives first.

85. In furtherance of the agreement between Dr. Leonard, Dr. Rowland, Dr. Wellman, and the Clinic, Dr. Leonard terminated Dr. Stratton's employment. Dr. Stratton's termination violated the Illinois Whistleblower Protection Act, which prohibits retaliation against any employee "for disclosing information to a government or law enforcement agency, where the employee has reasonable cause to believe that the information discloses a violation of . . . federal law, rule, or regulation." 740 Ill. Comp. Stat. 174/15.

86. Dr. Leonard, Dr. Wellman, Dr. Rowland, and the Clinic acted willfully and with malice in conspiring to terminate Dr. Stratton.

87. As a direct and proximate result of the foregoing, Dr. Stratton has lost the benefits and privileges of employment, and has suffered additional economic and non-economic damages, including severe emotional anguish, physical injury, and irreparable, continuing to harm her career.

WHEREFORE, Dr. Stratton respectfully requests that this Court enter judgment in her favor and against defendants Dr. Leonard, Dr. Wellman, and Dr. Rowland and Carle Clinic and provide the following relief:

(a) Award Dr. Stratton damages sufficient to compensate her for all lost wages and benefits she has and will continue to incur in an amount to be proved at trial;

(b) Enter an order reinstating Dr. Stratton to her former position;

(c) In the alternative, award Dr. Stratton damages for front pay and benefits in an amount to be proved at trial;

(d) Award Dr. Stratton punitive damages to the extent permitted by law;

(e) Award Dr. Stratton her costs and reasonable attorney fees;

(f) Award such other relief as the Court deems to be just.

COUNT III: CIVIL CONSPIRACY AGAINST DR. LEONARD, DR. WELLMAN, DR. ROWLAND, AND THE CLINIC FOR RETALIATORY DISCHARGE IN VIOLATION OF THE PUBLIC POLICY OF ILLINOIS

88. Plaintiff incorporates as though restated each of the allegations set forth in paragraphs 1 to 87 above.

89. Dr. Stratton repeatedly communicated and attempted to communicate to NCI, the FDA and OHRP her reasonable belief that the Clinic trials, as overseen by the Hospital Institutional Review Board, violated federal human research subject protection regulations. She reported her concerns to Dr. Minasian and Dr. Parnes at NCI about Dr. Rowland's interference with the Hospital Institutional Review Board's independence, in violation of 45 C.F.R. § 46.107(e); Dr. Rowland's concealing and failing to report information to the Institutional Review Board, thereby preventing reporting to OHRP and the FDA, in violation of 45 C.F.R. § 46.103(b)(5) and 21 C.F.R. § 56.113; and the Clinic and Hospital Institutional Review Board's creation of risks to patient safety in violation of the basic purpose of the regulations to protect human subject safety under 45 C.F.R. § 46.111(a)(1) and (2). At the time of her termination, Dr. Stratton was also attempting to ensure that the Hospital Institutional Review Board report the Clinic's failure to secure continued Institutional Review Board approval of the trials to the FDA or OHRP, as required by law, and that the Institutional Review Board properly audit the Clinic's files and report any further violations to the FDA and/or OHRP. In addition, Dr. Stratton

complained internally to Dr. Leonard, Dr. Wellman, Dr. Rowland, and other Hospital and Clinic officials about violations of the human research subject protections regulations.

90. Dr. Stratton informed Dr. Leonard about her complaints to NCI, her efforts to ensure proper Institutional Review Board reporting of violations of the human research subject protection regulations to the FDA and OHRP, and her intentions to audit the Clinic files, which would have lead to additional reports of violations to the Institutional Review Board, the NCI, the FDA, and OHRP. Dr. Stratton also informed the Clinic, Dr. Wellman, and Dr. Rowland about her efforts to ensure proper Hospital Institutional Review Board reporting of violations of the human research subject protection violations to the FDA and/or OHRP.

91. Dr. Leonard, the Hospital, Dr. Rowland, Dr. Wellman, and the Clinic agreed to retaliate against Dr. Stratton for her whistleblowing and prevent her from auditing the Clinic's files, which would have led to further reports of violations to the FDA and/or OHRP. Evidence of this agreement includes Dr. Leonard's admission to OHRP that he stopped Dr. Stratton's audit because he intended to meet with Clinic executives first.

92. Dr. Leonard, Dr. Wellman, Dr. Rowland, and the Clinic acted willfully and with malice in conspiring to terminate Dr. Stratton.

93. In furtherance of the agreement between Dr. Leonard, the Hospital, Dr. Rowland, Dr. Wellman, and the Clinic, Dr. Leonard and the Hospital terminated Dr. Stratton's employment just hours before she was to conduct the audit of the Clinic's files. Dr. Stratton's termination constituted the tort of retaliatory discharge in violation of the public policy of Illinois and a violation of the Illinois Whistleblower Act.

94. As a direct and proximate result of the foregoing, Dr. Stratton has lost the benefits and privileges of employment, and has suffered additional economic and non-economic

damages, including severe emotional anguish, physical injury, and irreparable, continuing to harm her career.

WHEREFORE, Dr. Stratton respectfully requests that this Court enter judgment in her favor and against defendants Dr. Leonard, Dr. Wellman, and Dr. Rowland and Carle Clinic and provide the following relief:

(a) Award Dr. Stratton damages sufficient to compensate her for all lost wages and benefits she has and will continue to incur in an amount to be proved at trial;

(b) Enter an order reinstating Dr. Stratton to her former position;

(c) In the alternative, award Dr. Stratton damages for front pay and benefits in an amount to be proved at trial;

(d) Award Dr. Stratton punitive damages to the extent permitted by law;

(e) Award Dr. Stratton her costs and reasonable attorney fees;

(f) Award such other relief as the Court deems to be just.

COUNT IV: TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE AGAINST DR. WELLMAN, DR. ROWLAND, AND THE CLINIC

95. Plaintiff incorporates as though restated each of the allegations set forth in paragraphs 1 to 94 above.

96. Dr. Stratton reasonably expected and intended that her employment at the Hospital would continue for the long-term, foreseeable future. She received excellent reviews and promotions during her tenure there. As recently as October 25, 2008, she emailed Dr. Leonard that she had a "long-term commitment" to remaining at the Hospital.

97. Dr. Wellman, Dr. Rowland, and the Clinic were all aware of Dr. Stratton's expectations to remain employed for the long term at the Hospital.

98. Dr. Stratton made clear to Dr. Wellman, Dr. Rowland, and the Clinic that she intended to fully pursue the Hospital Institutional Review Board and Clinic's regulatory compliance – including an audit of the Clinic's files. In order to keep Dr. Stratton from reporting regulatory violations, Dr. Wellman, Dr. Rowland, and the Clinic interfered with her employment by engineering her termination from the Hospital.

99. Dr. Leonard, Dr. Wellman, Dr. Rowland, and the Clinic acted willfully and with malice in interfering with Dr. Stratton's future employment with the Hospital.

100. As a direct and proximate result of the foregoing, Dr. Stratton has lost the economic benefits and privileges of employment, and has suffered additional economic and non-economic damages, including severe emotional anguish, physical injury, and irreparable, continuing to harm her career.

WHEREFORE, Dr. Stratton respectfully requests that this Court enter judgment in her favor and against defendants Dr. Leonard, Dr. Wellman, and Dr. Rowland and Carle Clinic and provide the following relief:

(a) Award Dr. Stratton damages sufficient to compensate her for all lost wages and benefits she has and will continue to incur in an amount to be proved at trial;

(b) Enter an order reinstating Dr. Stratton to her former position;

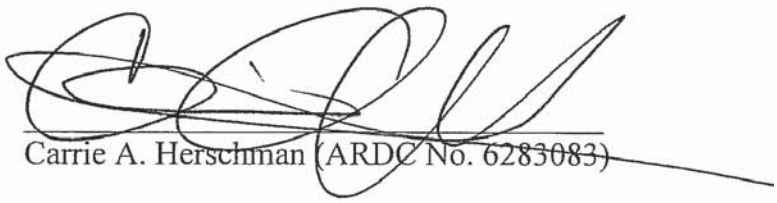
(c) In the alternative, award Dr. Stratton damages for front pay and benefits in an amount to be proved at trial;

(d) Award Dr. Stratton punitive damages to the extent permitted by law;

(e) Award Dr. Stratton her costs and reasonable attorney fees;

(f) Award such other relief as the Court deems to be just.

Respectfully submitted,



Carrie A. Herschman (ARDC No. 6283083)

November 5, 2009

Date

Penny Nathan Kahan (ARDC No. 03123818)
(Motion for Admission Pending)
Carrie A. Herschman (ARDC No. 6283083)
Penny Nathan Kahan & Associates, Ltd.
150 N. Wacker Drive
Suite 2236
Chicago, Illinois 60606
(312) 855-1660
pnk@pnkahan.com
cah@pnkahan.com

Debra S. Katz (D.C. Bar No. 411861)
(Motion for Admission Pending)
Lisa J. Banks (D.C. Bar No. 470948)
(Motion for Admission Pending)
Maura J. Dundon (D.C. Bar No. 982415)
(Motion for Admission Pending)
Katz, Marshall & Banks, LLP
1718 Connecticut Ave. NW
Washington D.C. 20009
(202) 299-1140
katz@kmblegal.com
banks@kmblegal.com
dundon@kmblegal.com

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS, URBANA DIVISION

M. SUZANNE STRATTON, PH.D.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
	)	
THE CARLE CLINIC ASSOCIATION,	)	
	)	
JAMES LEONARD, M.D.,	)	
Chief Executive Officer	)	
Carle Foundation Hospital	)	**JURY DEMAND**
	)	
BRUCE WELLMAN, M.D.	)	**Civil Action No. _____**
Chief Executive Officer	)	
Carle Clinic Association	)	
	)	
and	)	
	)	
KENDRITH ROWLAND, M.D.	)	
Cancer Center Program Director	)	
Carle Clinic Association	)	
	)	
Defendants.	)	
	)	

JURY DEMAND

Plaintiff demands a jury trial on all claims so triable.

Respectfully submitted,

Carrie A. Hersehman (ARDC No. 6283083)

November 5, 2015
Date

Penny Nathan Kahan (ARDC No. 03123818)
(Motion for Admission Pending)
Carrie A. Herschman (ARDC No. 6283083)
Penny Nathan Kahan & Associates, Ltd.
150 N. Wacker Drive
Suite 2236
Chicago, Illinois 60606
(312) 855-1660
pnk@pnkahan.com
cah@pnkahan.com

Debra S. Katz (D.C. Bar No. 411861)
(Motion for Admission Pending)
Lisa J. Banks (D.C. Bar No. 470948)
(Motion for Admission Pending)
Maura J. Dundon (D.C. Bar No. 982415)
(Motion for Admission Pending)
Katz, Marshall & Banks, LLP
1718 Connecticut Ave. NW
Washington D.C. 20009
(202) 299-1140
katz@kmblegal.com
banks@kmblegal.com
dundon@kmblegal.com