

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

DEC 18 2013

JAMES H. PATTEN, Clerk
Deputy Clerk

ANA M. ABREU-VELEZ, M.D.,)
Ph.D.,)

Plaintiff,)

v.)

BOARD OF REGENTS OF THE)
UNIVERSITY SYSTEM OF)
GEORGIA; GEORGIA)
REGENTS UNIVERSITY,)
formerly known as Medical)
College of Georgia; and EMORY)
UNIVERSITY;)

Defendants.)
_____)

Civil Action File No.

1 13-CV-4187

COMPLAINT

COMES NOW Plaintiff, Ana M. Abreu-Velez, M.D., Ph.D. ("Plaintiff"
and/or "Dr. Abreu-Velez"), and, files this her Complaint against the Defendants
Board of Regents of the University System of Georgia; Georgia Regents

University, formerly known as Medical College of Georgia¹; and Emory University (collectively, “Defendants”), and shows the Court as follows:

Jurisdiction and Venue

1.

This lawsuit arises under 42 U.S.C. §§ 1983 and 1988 for the deprivation of rights guaranteed to Plaintiff under the 1st, 5th and 14th Amendments to the United States Constitution and the Constitution of the State of Georgia and O.C.G.A. § 45-1-4, known as the Georgia Whistleblower Act.

2.

This Court has subject-matter jurisdiction of this action as a claim arising under federal law and pursuant to 28 U.S.C. § 1343.

3.

Venue is proper in this Court.

¹ Georgia Regents University, formerly known as Medical College of Georgia, is a department/division within the Board of Regents of the University System of Georgia.

Parties

4.

Dr. Abreu-Velez is a person within the jurisdiction of the United States whose rights, privileges, and immunities under federal and state law were violated by the Defendants, who are acting under color of law.

5.

Defendant Board of Regents of the University System of Georgia (“Board of Regents”) is made a party to this action as the entity that created and operates Georgia Regents University (“GRU”), formerly known as Medical College of Georgia (“MCG”). Pursuant to § 12.6 of the Bylaws of the Board of Regents, process of service may be perfected on the Board of Regents by delivery of a copy of this Complaint , together with the summons, to the Board’s Secretary or Assistant Secretary at 270 Washington Street, S.W., Atlanta, Georgia 30334.

6.

Defendant GRU is a university created and operated by the Board of Regents. Process of service may be perfected on GRU by delivery of a copy of this Complaint, together with the summons, to GRU’s President and CEO, Ricardo Azziz, M.D., MPH, MBA, at 1120 15th Street, Augusta, Georgia 30912.

7.

Defendant Emory University is a non-profit corporation organized under the laws of the State of Georgia ("Emory University"). Process of service may be perfected on Emory University by delivery of a copy of this Complaint, together with the summons, to its registered agent Melinda Simon, 201 Dowman Drive, 101 Administration Building, Atlanta, Georgia 30322.

Statement of the Facts

8.

Dr. Abreu-Velez was employed in various departments of MCG from October, 2001. On August 8, 2004, Dr. Abreu-Velez was hired as a research assistant and study coordinator by Dennis Marcus, M.D., working in the MCG Department of Ophthalmology ("Dr. Marcus") (hereafter the Department of Ophthalmology shall be referred to as the "Department").

9.

One of the duties assigned to Dr. Abreu-Velez by Dr. Marcus was study coordinator for the Theragenics, Inc. clinical trials being conducted by the Department.

10.

Theragenics, Inc. is a pharmaceutical company that finances studies relating to ophthalmology with various medical schools in the United States (“Theragenics”).

11.

Dr. Marcus applied for, and received, a grant from Theragenics to conduct a clinical study on humans that involved radiation and invasive surgery to be performed at MCG (“Theragenics Study”).

12.

Dr. Marcus was named the principal investigator of the Theragenics Study and had ultimate responsibility for ensuring that the Theragenics Study complied with all federal and state rules, laws and regulations applying to clinical trials.

13.

As principal investigator, Dr. Marcus was also responsible for:

(a) the safety of MCG employees involved in the procedures and in conducting the Theragenics Study;

(b) the training of those employees who would work in any part of the Theragenics Study;

(c) the safety during training of those employees who would work in any part of the Theragenics Study; and

(d) ensuring that, during the training and in the conduct of the Theragenics Study, the facilities would be used in a manner which was safe for all persons who would be involved in the Theragenics Study, including employees and participants.

14.

Part of Dr. Abreu-Velez's job duties, as noted in a letter written by Dr. Marcus dated October 27, 2004, to Brigitte Taylor, in the Office of Clinical Trials Compliance ("OCTC"), and Dr. George Schuster, was "to help support compliance in these studies."

15.

While working as research assistant and study coordinator under Dr. Marcus and in the Department, Dr. Abreu-Velez noted numerous aspects of the Theragenics Study which she found to be in violation of the federal and state rules, laws and regulations applying to clinical trials. These violations included, but were not limited to, kickbacks being given to the physicians at MCG; violations related to the use of radiation (which misuse can cause serious injury or even death); violations of the laws, rules and regulations concerning the use of radiation; violations of the laws, rules and regulations in conducting the training; violations

in safety requirements related to the facilities to be used in the Theragenics Study; and violations related to the billing of persons participating in the Theragenics Study.

16.

Dr. Abreu-Velez reported these violations at an early stage during her employment in the Department, including reporting the violations directly to Dr. Marcus. As early as October 15, 2004, Plaintiff made her complaints known to Dr. Julian Nussbaum, the Director of the Department.

17.

In preparation for a training session related to the Theragenics Study which was to take place on November 19, 2004, Dr. Marcus sent an e-mail notice on November 18, 2004, to various departments and personnel of MCG and to Theragenics personnel setting up the training session for mid-afternoon on the 19th and requiring the attendance of some of those persons. There were objections to the scheduled training , and a meeting was scheduled for the morning of November 19. Most of the persons attending the meeting had formal training in the safety procedures in their area of expertise, including the applicable federal and state rules, laws and regulations. At the meeting, the attendees agreed that the meeting could not go forward without jeopardizing the health and safety of those involved

in the training and, ultimately, the human subjects who would participate in the clinical trials.

18.

By e-mail dated the morning of November 19, 2004, Dr. Abreu-Velez reported to Dr. Marcus the determination by those attending the meeting that the training session should not go forward that afternoon. The e-mail had attached thereto a list of the concerns addressed by those attending the meeting, including the need for TB tests and the results of those tests; the need for distribution of radiation detection badges issued prior to the training session; and other safety issues which were controlled by the applicable federal and state rules, laws and regulations. The e-mail included the signatures of management personnel. In her e-mail notice to Dr. Marcus, Dr. Abreu-Velez stated that, as the formally-appointed clinical supervisor of the Theragenics Study, and under her license and degrees, she could not authorize that the training session go forward.

19.

Following the receipt of the e-mail notice referenced in Par. 18 above and on November 19, 2004, Dr. Marcus stormed into Dr. Abreu-Velez's office, angrily told her she should not have sent the e-mail, and instructed her to go home.

20.

Later on the afternoon of November 19, 2004, Dr. Abreu-Velez was informed via a telephone call from an agent of MCG that, at the direction of Dr. Marcus, her employment had been terminated effective November 22, 2004.

21.

Following her termination, Dr. Abreu-Velez was referred to Mr. Newton, MCG legal advisor, who requested that she work with him by telling him everything she believed to be wrong with the Department's procedures, training and conduct of the Theragenics Study.

22.

From January 2005 through about June 2005, Dr. Abreu-Velez provided Mr. Newton with information and documents which she had gathered, much of which is Dr. Abreu-Velez's intellectual property needed for further research which she was conducting. Dr. Abreu-Velez's personal intellectual property has never been returned to her.

23.

As a result of Dr. Abreu-Velez's revelation of the problems with the Department's procedures and with the Theragenics Study, MCG initiated changes in personnel and job responsibilities.

24.

Mr. Newton referred Dr. Abreu-Velez to Phil McGuire at MCG who was to assist her in finding another position at MCG. Dr. Abreu-Velez applied for numerous positions at MCG during the year 2005. She has evidence of the positions applied for and that she did not receive any offers for any of those positions.

25.

While working at MCG in the Department, Dr. Abreu-Velez exposed that multiple pharmaceutical companies paid off physicians at MCG and hospitals to induce them to prescribe several medications and brachytherapy, in violation of the False Claims Act. As a result of not following the proper rules in clinical trials, 12 patients died and/or suffered severe adverse events ("SAEs"). These SAEs were not reported to the Federal Drug Administration ("FDA"), which is also illegal, and resulted in giving contraindicated medications to the patients. In the 2005 Abreu-Velez Lawsuit, Dr. Abreu-Velez proved that MCG forged patient care forms in an attempt to cover up these illegal activities.

26.

In the fall of 2005, Dr. Abreu-Velez found employment at Emory University's School of Medicine, a unit of Emory University.

27.

On or about November 17, 2005, Dr. Abreu-Velez, through counsel, filed a lawsuit against the Board of Regents, MCG and Dr. Marcus in the United States District Court, Southern District, Augusta Division, Civil Action File No. CV1:05-186 ("2005 Abreu-Velez Lawsuit"). Upon Motion for Summary Judgment, judgment was entered by Judge J. Randall Hall against Dr. Abreu-Velez, and her case was dismissed on February 12, 2009 ("Judgment"). Dr. Abreu-Velez pursued an appeal of the Judgment; however, the appeal was unsuccessful.

28.

During the years 2008 and 2009, many of the employees involved in clinical trials at MCG, including Dr. Marcus, were either fired or voluntarily resigned their positions, which events Dr. Abreu-Velez asserts, upon information and belief, is a result of her reporting the irregularities in clinical trials during her employment in the Department and upon termination from her employment with MCG.

29.

After being terminated from her employment with MCG, Dr. Abreu-Velez reported the irregularities in conducting clinical trials, including the Theragenics Study, to the Federal Bureau of Investigation ("FBI").

30.

Dr. Daniel Rhan, President of MCG at the time of Dr. Abreu-Velez's employment with MCG, resigned his position in October, 2009, which Dr. Abreu-Velez asserts, upon information and belief, is a result of her reporting the irregularities in clinical trials being conducted at MCG to the FBI.

31.

During the years 2009 and 2010, Dr. Barry Goldstein, MCG Provost, CEO Don Snell, and Dr. George Shuster, MCG Director of Clinical Trials, upon information and belief of Dr. Abreu-Velez, were forced to resign from MCG, and, Plaintiff asserts, upon information and belief, that these events are a result of her reporting the irregularities in clinical trials being conducted at MCG to the FBI.

32.

Dr. Abreu-Velez applied for a renewal of her Green Card status in the United States, and, upon Dr. Abreu-Velez's information and belief, Dr. Thomas Lawley, Dean of the Emory School of Medicine ("Dr. Lawley"), and those employed in Emory University's Human Resources Department, interfered with

the processing of the application. In February 2012, Dr. Abreu-Velez reported this event to the FBI and to the U.S. Attorney's office in Atlanta.

33.

A jury trial was denied to Plaintiff, both at the trial court level in Augusta and the appellate level in Atlanta. In an ethical and just system, Dr. Abreu-Velez would have been afforded a jury trial, and the jury would have evidence to support her reinstatement at MCG with back pay and such benefits as Dr. Abreu-Velez would have enjoyed had she not been improperly terminated.

34.

Dr. Abreu-Velez was retaliated against for making disclosures under O.C.G.A. § 45-1-4, specifically O.C.G.A. § 45-1-4(e) (2) (D) and (E). Dr. Abreu-Velez is thus entitled to reinstatement with GRU, as well as restoration of all benefits of employment lost as a result of her termination as provided under O.C.G.A. § 45-1-4(e) (2) (B) and (C). Dr. Abreu-Velez is also entitled to recover attorney's fees and all costs of litigation under O.C.G.A. § 45-1-4(f).

35.

Both MCG and Emory School of Medicine have obtained grants for clinical trials through Theragenics, and, upon information and belief, officials at MCG and Emory School of Medicine, worked together to thwart Dr. Abreu-Velez's right to remain in the United States and to disparage her reputation in the field of medicine

in the State of Georgia, thus conspiring against Dr. Abreu-Velez and continuing their illegal activities against her in violation of 42 U.S.C. §§ 1983 and 1988 for the deprivation of rights guaranteed to her under the 1st, 5th and 14th Amendments to the United States Constitution and the Constitution of the State of Georgia.

36.

In late 2011, Dr. Lawley announced his resignation from the Emory School of Medicine, and Dr. Abreu-Velez believes this to be a result of her reporting the irregularities in clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney.

37.

At least two (2) persons employed in Emory University's Human Resources Department were dismissed from employment, and Dr. Abreu-Velez believes these events to be a result of her reporting the irregularities in clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney and Emory University's collusion with MCG against Dr. Abreu-Velez.

38.

Dr. Abreu-Velez's green card application, which had contained errors which were the fault of Emory University, including the fact that several documents were removed from her file, was corrected in 2012, as a result of the efforts of the FBI.

39.

In January 2013, one week after Dr. Lawley had left his position with Emory School of Medicine, Judge Joel F. Dubina, who had been assigned to Dr. Abreu-Velez's appeal in the U.S. Court of Appeals, 11th Circuit, announced his resignation as chief judge. Following the denial of her appeal to the U.S. Court of Appeals, Dr. Abreu-Velez made a formal complaint to the Georgia Judicial Commission, and, upon information and belief, Dr. Abreu-Velez asserts that Judge Dubina's resignation is a result of her complaint, her reporting the irregularities in clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney, and Judge Dubina's relationship with Dr. Lawley and other persons of power at Emory University. Judge Dubina, who began his term July 1, 2009, served only four (4) years of the 7-year term to which he was appointed.

40.

Shortly after Dr. Lawley's resignation, U.S. Senator Saxby Chambliss announced that he would not run again for election to his position, and Dr. Abreu-Velez believes this to be a result of her reporting the irregularities in clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney and that Dr. Abreu-Velez had reported the multiple documented attacks against person and property affecting Dr. Abreu-Velez and her family which she believes to be orchestrated by Emory University and MCG.

41.

One such attack against Dr. Abreu-Velez and her family occurred on or about March 30, 2006, when her daughter, Manuela, was physically attacked and hospitalized with injuries for a month, which, upon Dr. Abreu-Velez's information and belief, is in retaliation for her reporting the irregularities in clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney. Attacks upon her person and property, have continued, and still continue, and Dr. Abreu-Velez believes these attacks to be perpetrated by MCG and/or Emory University.

42.

In May, 2013, C.R. Bard, Inc., a sister company to Theragenics, settled with the U.S. Department of Justice for giving kickbacks to physicians, similar to the situation revealed by Dr. Abreu-Velez in 2004 and which was part of her claims in her 2005 Abreu-Velez Lawsuit. Frauds were committed by triple, and sometimes quadruple, illegal payments resulting in fraud against the federal and state governments, including Medicare and Medicaid.

43.

In August, 2013, Theragenics CEO M. Christine Jacobs, announced her retirement, which Dr. Abreu-Velez believes is a result of her reporting the irregularities, including violations of laws, rules, and regulations in clinical trials at

MCG and the laundering of money at MCG, in the Theragenics Study and clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney

44.

On or about August 8, 2013, the office of the U.S. Attorney announced a settlement by which Emory University was to pay \$1.5 million in a lawsuit filed by Elizabeth E. Elliott, former billing clerk with Emory, Civil Action File No. 1:09-cv-3569, alleging violations of the False Claims Act in medical clinical trials at Emory University and subsidiaries of Emory University, including Emory School of Medicine (“Elliott v. Emory University Lawsuit”).

45.

Upon information and belief, Emory University is the headquarters for Theragenics’s clinical trials in Georgia. Both MCG and Emory University and/or Emory School of Medicine were provided grants by Theragenics for the clinical trials.

46.

The filing and settlement of the Elliott v. Emory University Lawsuit supports and proves Dr. Abreu-Velez’s previous assertions in the 2005 Abreu-Velez Lawsuit that MCG was, through Medicaid and Medicare, improperly billing participants in the Theragenics Study.

47.

Since Dr. Abreu-Velez contacted the FBI and gave them documentation related to (a) the improper billing by MCG in violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1; (b) laundering of money through residual accounts and through MCG Foundation; and (c) violations of federal law, rules and regulations, medical clinical trials in Georgia from 2006 through 2013, have greatly improved by the addressing of practices adversely affecting the quality of patient care, medical research, and education, and Dr. Abreu-Velez asserts that, upon information and belief, these improvements are a result of her reporting the irregularities in clinical trials being conducted at MCG to the FBI.

48.

The consolidated 2004-2013 evidence shows that (a) more than 50 people left MGC and Emory University; (b) rules in clinical trials and in clinical trial billings were changed both at MCG and Emory University; and (c) Dr. Abreu-Velez and her family experienced multiple attacks for over eight (8) years.

49.

Plaintiff suffered, and continues to suffer, injury to her professional reputation as a result of the retaliatory acts advanced by Emory University and MCG, because of her efforts, while at MCG, to bring to MCG's attention the irregularities in the Theragenics Study and other clinical trials and her reporting the

irregularities in the Theragenics Study and clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney.

50.

Plaintiff has suffered loss of income, including insurance benefits and other employee benefits, which she received as an employee of MCG, as a result of her efforts, while at MCG, to bring to MCG's attention the irregularities in the Theragenics Study and other clinical trials and her reporting the irregularities in the Theragenics Study and clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney.

51.

Plaintiff will continue to suffer loss of future income as a result of her efforts, while at MCG, to bring to MCG's attention the irregularities in the Theragenics Study and other clinical trials and her reporting the irregularities in the Theragenics Study and clinical trials conducted at MCG to the FBI and the office of the U.S. Attorney.

52.

The acts of Dr. Marcus, as an employee of MCG, and of other MCG employees and officials, were in willful and wanton disregard of the rights of Dr. Abreu-Velez.

53.

The acts of Emory University, via its employees and representatives, were in willful and wanton disregard of the rights of Dr. Abreu-Velez.

54.

Based on the continued retaliation by MCG and Emory University, working in collusion with MCG against Dr. Abreu-Velez, she continues to suffer injuries in violation of 42 U.S.C. §§ 1983 and 1988 for the deprivation of rights guaranteed to Plaintiff under the 1st, 5th and 14th Amendments to the United States Constitution and the Constitution of the State of Georgia.

56.

Based on the new evidence revealed by the chain of events following Dr. Abreu-Velez's termination from employment with MCG and the settlement of the Elliott v. Emory University Lawsuit, Dr. Abreu-Velez seeks damages for the injuries suffered by her in violation of 42 U.S.C. §§ 1983 and 1988 for the deprivation of rights guaranteed to Plaintiff under the 1st, 5th and 14th Amendments to the United States Constitution and the Constitution of the State of Georgia.

COUNT ONE – First Amendment Claim

57.

Plaintiff incorporates the facts set forth in each and every paragraph numbered 1 through 56 above, as if set forth verbatim herein.

58.

Plaintiff, pursuant to her rights under the 1st Amendment of the United States Constitution, engaged in speech that was a matter of public importance and concern; she was voicing concerns of others in a matter of public importance in an effort to protect the participants in the Theragenics Study and other clinical trials at MCG and the public, and such speech is a protected right of Plaintiff.

59.

In retaliation for the advancement of her right of free speech, Dr. Marcus, and others unknown to Plaintiff, acting on behalf of MCG, and Emory University in its conspiracy to assist MCG in its retaliation against Plaintiff, willfully and wantonly deprived Dr. Abreu-Velez of her right of freedom of speech with regard to matters of public concern and safety for the public and those persons participating in the Theragenics Study and other clinical trials at MCG, which acts by MCG are not consistent with the due process of law and equal protection of the laws and thereby chilling Dr. Abreu-Velez's First Amendment rights.

60.

The continued retaliation against Dr. Abreu-Velez by MCG and by Emory University and Emory School of Medicine is in violation of the rights afforded to Plaintiff under 42 U.S.C. §§ 1983 and 1988, the 1st, 5th and 14th Amendments to the United States Constitution and the Constitution of the State of Georgia.

COUNT TWO – Georgia Whistleblower Claim

61.

Plaintiff incorporates the facts set forth in each and every paragraph numbered 1 through 60 above, as if set forth verbatim herein.

62.

Dr. Abreu-Velez was a public employee working for a public employer as provided under O.C.G.A. § 45-1-4.

63.

Dr. Abreu-Velez was an employee protected by O.C.G.A. § 45-1-4 from retaliation by Dr. Marcus, acting on behalf of MCG, and others unknown to Plaintiff, acting on behalf of MCG, and Emory University in its conspiracy to assist MCG in its retaliation against Plaintiff, for reporting violations to Dr. Marcus, her supervisors at MCG and other officers and employees of MCG, of the rules, regulations and laws related to clinical trials in Georgia.

64.

Dr. Marcus and his superiors and supervisors at MCG were aware that she reporting the violations noted in this Complaint. As a result of her reporting these violations, Dr. Marcus, acting on behalf of MCG, wrongfully caused the termination of Dr. Abreu-Velez's employment at MCG.

65.

Persons unknown to Plaintiff, acting as employees or agents of MCG, caused Dr. Abreu-Velez not be reinstated or hired for another position at MCG, which is adverse employment action pursuant to O.C.G.A. § 45-1-4.

66.

The retaliation against Dr. Abreu-Velez for making disclosures protected under O.C.G.A. § 45-1-4, specifically O.C.G.A. § 45-1-4(e) (2) (D) and (E) entitles her to reinstatement with GRU as well as all benefits of employment lost as a result of her termination as provided under O.C.G.A. § 45-1-4(e) (2) (B) and (C).

67.

The continued retaliation against Dr. Abreu-Velez by MCG and by Emory University and Emory School of Medicine is in violation of O.C.G.A. § 45-1-4(e), and Dr. Abreu-Velez has and will suffer damages as a result of same.

WHEREFORE, Plaintiff prays:

- (a) That process issue in accordance with the law;
- (b) That defendants be enjoined from further retaliatory acts against Plaintiff;
- (c) That Plaintiff be awarded such special damages as are proven at trial;
- (d) That Plaintiff be awarded compensatory damages against the Defendants, jointly and severally;

- (e) That Plaintiff be awarded punitive damages against each Defendant;
- (f) That the Court award damages to Plaintiff under O.C.G. A. § 45-1-4(e)(2), including reinstatement, back pay and all benefits lost to her as a result of her termination;
- (g) That her intellectual property held by MCG be returned to her;
- (h) That the Court award costs of this action under 42 U.S.C. § 1988 and O.C.G.A. § 45-1-4(f) to Plaintiff; and
- (i) That the Court award such other and further relief to Plaintiff as it deems just and proper.

A trial by jury is demanded.

This 18th day of December, 2013.


Ana M. Abreu-Velez, *pro se*