

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively the “United States”), Emory University, Emory Healthcare, Inc., and The Emory Clinic, Inc. (collectively “Emory”), and Elizabeth E. Elliott (“Relator”) (hereafter collectively referred to as “the Parties”), by and through their authorized representatives.

RECITALS

A. Emory operates an academic medical center and offers numerous clinical trials to patients through Emory and its partner institutions. The Winship Cancer Institute (“Winship”) is an operating division of Emory, and participates in oncology clinical research trials with the goal of advancing progress in cancer care.

B. On December 18, 2009, Relator Elizabeth Elliott, a former Clinical Research Finance Manager at Emory, filed a qui tam action in the United States District Court for the District of the Northern District of Georgia captioned *United States of America and State of Georgia ex rel. Elizabeth Elliott v. Emory University, Robert W. Woodruff Health Sciences Center, Emory Healthcare, Inc., Emory University School of Medicine, Grady Memorial Hospital, Inc., and The Emory Clinic, Inc.*, Civ. No. 1:09-cv-3569-AT, N.D. Ga. (Under Seal) pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). In her Complaint, Relator alleges that Emory submitted false claims to the United States and the State of Georgia by billing Medicare and Georgia Medicaid for clinical trial services that should have been billed to

clinical trial sponsors and billing Medicare and Georgia Medicaid as well as the clinical trial sponsors.

C. The United States contends that Emory submitted or caused to be submitted claims for payment to the Medicare Program (“Medicare”), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1, and the Medicaid Program (“Medicaid”), 42 U.S.C. §§ 1396-1396w-5.

D. The United States contends that Emory submitted or caused to be submitted certain claims to Medicare and Medicaid for clinical trial services that were billed in violation of the National Coverage Determination for Clinical Trials (“NCD”). These claims relate to the oncology clinical trials at Winship which began on or between January 1, 2001 through December 31, 2010, from which the United States selected a sample and conducted billing reviews. This conduct is referred to below as the “Covered Conduct.”

E. This Settlement Agreement is neither an admission of liability by Emory nor a concession by the United States that its claims are not well founded.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Emory shall pay to the United States America one million, four hundred twenty nine thousand, nine hundred seventy-two dollars and ninety-five cents (\$1,429,972.95) plus interest accrued at the annual rate of 1.5% from March 15, 2013, to the effective date of this Settlement Agreement (collectively, the "Federal Settlement Amount") no later than fifteen (15) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Northern District of Georgia.

Emory also agrees to pay to the State of Georgia Department of Community Health seventy thousand, twenty-seven dollars and five cents (\$70,027.05), plus interest accrued at the annual rate of 1.5% from March 15, 2013, to the effective date of this Settlement Agreement (collectively, the "Medicaid State Settlement Amount"). The specific terms of Emory's settlement with State of Georgia Medicaid Fraud Control Unit are set forth in a separate agreement.

2. Conditioned upon Relator's filing a stipulation of dismissal with prejudice of all claims in the Civil Action as set forth in Paragraph 14 and Relator's release as set forth in Paragraph 4 of this Agreement, Emory shall pay to the Relator Three Hundred Twenty Two Thousand Five Hundred Dollars (\$322,500) no later than fifteen (15) days after the Effective Date of this Agreement by wire transfer to Relator's counsel, Bothwell Bracker, for expenses, attorneys' fees and costs, and shall also pay to the Relator Eleven Thousand Two Hundred Fifty Dollars (\$11,250) by wire transfer to Relator's counsel, Bothwell Bracker, for wrongful termination claims under subsection 3730(h).

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Emory's full payment of the Federal Settlement Amount, the United States releases Emory, together with its current and former officers, directors, trustees, employees, agents, and shareholders, as well as any direct or indirect subsidiaries, divisions and affiliates from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Conditioned upon Emory's full payment of the Federal Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Emory, together with its current and former officers, directors, trustees, employees, agents and shareholders, as well as its and any direct or indirect subsidiaries, divisions, affiliates, successors, assigns, and attorneys from all claims, whether known or unknown as of the Effective Date of this Agreement that Relator has, may have, could have asserted, or may assert in the future on her behalf or on behalf of the United States, including but not limited to any claim relating in any way to the Covered Conduct, the allegations of the Complaint, Relator's employment by Emory, the filing of the Civil Action, the investigation and prosecution of this matter, or the negotiation of this Agreement, including all liability, claims, demands, actions or causes of action existing as of the Effective Date of this Agreement, fixed or contingent, in law or in equity, in contract or in tort, or under any federal or state statute, regulation, or common law. Relator acknowledges and agrees that she is not eligible for re-hire and will not apply for

or accept employment with Emory University, Emory Healthcare, or any of their affiliates.

5. Notwithstanding the releases given in paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; or
- f. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement, but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and this Civil Action, Relator and her heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Action in order to dismiss the Civil Action, nor any dismissal of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and

3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and his/her heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his/her claim(s).

7. Conditioned upon Relator's receipt of the payments described in Paragraph 2 above, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Emory, together with its current and former officers, directors, trustees, employees, agents, and shareholders, as well as any direct or indirect subsidiaries, divisions and affiliates from any claim she has, may have, could have asserted, or may assert in the future, on behalf of herself or on behalf of any other person for any liability to Relator or her attorney arising from the filing of the Civil Action or the negotiation of this Agreement, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

8. Emory waives and shall not assert any defenses Emory may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Federal Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. Emory fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Emory has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. The Federal Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any State payer, related to the Covered Conduct; and Emory agrees not to resubmit to any Medicare contractor or any State payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

11. Emory agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Emory, its present or former officers, directors, trustees, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

- (3) Emory's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
 - (4) the negotiation and performance of this Agreement;
 - (5) the payment Emory makes to the United States pursuant to this Agreement and any payments that Emory may make to Relator, including costs and attorneys' fees.
- b. Future Treatment of Unallowable Costs: If applicable, unallowable Costs shall be separately determined and accounted for by Emory, and Emory shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Emory or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Emory further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to,

payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Emory or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Emory agrees that the United States, at a minimum, shall be entitled to recoup from Emory any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Emory or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Emory or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Emory's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 13 (waiver for beneficiaries paragraph), below.

13. Emory agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement which are prior to January 1, 2011, from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

14. After the Effective Date of this Agreement, the United States shall promptly file in the Civil Action a Notice of Intervention as to the Covered Conduct. Upon receipt of the Federal Settlement Amount, the United States and Relator also shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Action pursuant to Rule 41(a)(1), as follows:

- a. the Stipulation of Dismissal shall be with prejudice as to the Relator's claims, pursuant to and consistent with the terms and conditions of this Agreement;
- b. the Stipulation of Dismissal shall be with prejudice as to the United States' claims as to the Covered Conduct, pursuant to and consistent with the terms and conditions of this Agreement;
- c. the Stipulation of Dismissal shall be without prejudice as to the United States as to all other claims, pursuant to and consistent with the terms and conditions of this Agreement.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Northern District of Georgia. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

21. This Agreement is binding on Emory's successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

23. In consideration for the payments made by Emory to Relator set forth in Paragraph 2 of this Agreement, the Relator will keep the facts and terms of the Agreement confidential. The Relator will not issue any press release, participate in any media interview, or make any statement to the media in any form regarding the fact and

terms of the Agreement or the Covered Conduct. The Relator may only disclose the fact and/or terms of the Agreement pursuant to an appropriate order or lawful subpoena from a court or other agency with competent jurisdiction. The Relator upon receiving such subpoena or notice that such an order is being sought shall promptly provide Emory with written notice to allow Emory reasonable opportunity to object or otherwise seek relief from disclosure.

24. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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signatures to follow

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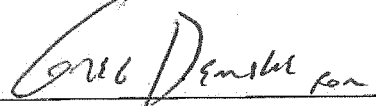
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THE UNITED STATES OF AMERICA

SALLY QUILLIAN YATES
UNITED STATES ATTORNEY

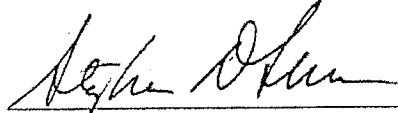
DATED: 8/28/13 BY: 
DARCY F. COTY
Assistant U.S. Attorney
United States Attorney's Office
Northern District of Georgia

DATED: 8/27/13 BY: 
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

EMORY UNIVERSITY - DEFENDANT

DATED: 8/23/2013

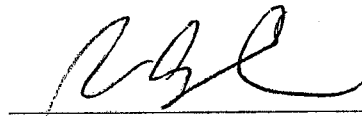
BY:



STEPHEN D. SENCER
Sr. Vice President and General Counsel
Emory University

DATED: 8/26/13


BY:



RICHARD L. SHACKELFORD
PHYLLIS B. SUMNER
MICHAEL E. PAULHUS
King & Spalding LLP
Counsel for Emory University

ELIZABETH E. ELLIOTT - RELATOR

DATED: 8/22/13

BY: 
ELIZABETH E. ELLIOTT
Relator

DATED: _____

BY: _____
MIKE BOTHWELL
Bothwell Bracker
Counsel for Relator

DATED: _____

BY: _____
JAMES (JAY) SADD
Slaphey & Sadd, LLC
Counsel for Relator

DATED: _____

BY: _____
KURT S. SCHULZKE
Slaphey & Sadd, LLC
Counsel for Relator

ELIZABETH E. ELLIOTT - RELATOR

DATED: _____

BY: _____
ELIZABETH E. ELLIOTT
Relator

DATED: 8/22/13

BY: Mike Bothwell
MIKE BOTHWELL
Bothwell Bracker
Counsel for Relator

DATED: 8.22.13

BY: [Signature]
JAMES (JAY) SADD
Slappey & Sadd, LLC
Counsel for Relator

DATED: _____

BY: _____
KURT S. SCHULZKE
Slappey & Sadd, LLC
Counsel for Relator

ELIZABETH E. ELLIOTT - RELATOR

DATED: _____

BY: _____

ELIZABETH E. ELLIOTT
Relator

DATED: _____

BY: _____

MIKE BOTHWELL
Bothwell Bracker
Counsel for Relator

DATED: _____

BY: _____

JAMES (JAY) SADD
Slappey & Sadd, LLC
Counsel for Relator

DATED: 8-22-13

BY: 

KURT S. SCHULZKE
Slappey & Sadd, LLC
Counsel for Relator