

State of North Carolina

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North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Thom Tillis
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Stan Bingham
Senator Buck Newton
Representative Jamie Boles
Representative N. Leo Daughtry
Representative John Faircloth
Representative Pat Hurley
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Endo
Pharmaceuticals, Inc.

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A Settlement Agreement has been executed between Endo Pharmaceuticals, Inc. and the State of North Carolina. Endo is a Delaware corporation headquartered in Malvern, Pennsylvania and is a wholly owned subsidiary of Endo Health Solutions, Inc.


The settlement resolves allegations that from March 1999 through December

2007, Endo off-label marketed its drug Lidoderm for conditions for which it had not been approved by the Food and Drug Administration.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$1,565,007.92. Of that amount the federal government will receive \$994,431.50 for federal health care programs and North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$95,889.41 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$192,573.43 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$263,574.19 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$7,671.47 for investigative costs and \$10,867.91 for costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,


Kristi Jones
Chief of Staff

KJ:ng

cc: Kristine Leggett, NCGA Fiscal Research Division
Christy Agner, NCDOJ, Legislative Liaison
Nels Roseland, NCDOJ, Deputy Chief of Staff

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Endo Health Solutions Inc. ("Endo Health Solutions") and Endo Pharmaceuticals Inc. ("Endo") (collectively "Defendants"); hereinafter collectively referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Endo is a Delaware corporation headquartered in Malvern, Pennsylvania and is a wholly owned subsidiary of Endo Health Solutions Inc. At all relevant times, Defendants distributed, marketed and sold pharmaceutical products in the United States, including a drug approved for the treatment of pain associated with post-herpetic neuralgia sold under the trade name of Lidoderm. From September 1999 through the present, Defendants manufactured, marketed, and sold Lidoderm.

B. On or about July 5, 2005, Relator Ryan filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex. rel Peggy Ryan v. Endo Pharmaceuticals Inc., Civil Action No. 05CV3450. On or about March 29, 2009, Relator Ryan filed an Amended Complaint adding additional counts under the false claims statutes for New York and Florida. On or about September 4, 2010, Relator Ryan filed a Second Amended Complaint (the "Ryan Civil

Action”) setting forth the allegations in her *qui tam* action and adding additional counts under the false claims statutes for the Massachusetts, California, Virginia, Delaware, Illinois, Nevada, Georgia, Hawaii, Indiana, Montana, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, Tennessee and Texas. On or about May 4, 2010, Relator Weathersby filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned United States ex rel. Weathersby v. Endo Pharmaceuticals, Inc., et al. Civil Action No. 10-2039, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). On or about December 21, 2011, Relator Weathersby amended his Complaint a third time, adding Relator MK Litigation Partnership, LLP, and this Third Amended Complaint sets forth the allegations in their *qui tam* action (the “Weathersby Civil Action”). The Ryan Civil Action and the Weathersby Civil Action are collectively the “Civil Actions.”

C. Defendants have entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the United States of America (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the “United States.”

D. The State contends that Defendants caused claims for payment to be submitted to the State’s Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).

E. The State contends that it has certain civil and administrative causes of action against Defendants for engaging in the following conduct (the “Covered Conduct”):

Between March 1999 and December 2007, Endo knowingly promoted the sale and use of Lidoderm for conditions for which it had not been approved by the

United States Food and Drug Administration (FDA), including for use in connection with lower back pain and chronic pain, which were not medically-accepted indications (as defined in 42 U.S.C. § 1396r-8(k)(6)), and were not covered by state Medicaid programs and these prescriptions were reimbursed by state Medicaid programs.

As a result of the foregoing conduct (referred to hereafter as the "Covered Conduct"), the State alleges that Defendants knowingly caused false and/or fraudulent claims for Lidoderm to be submitted to, or caused purchases by, the State's Medicaid program.

F. This Agreement is neither an admission of facts or liability by Defendants, nor a concession by the State that its allegations are not well founded. The Defendants expressly deny the allegations of the State as set forth herein and in the Civil Actions.

G. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendants agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of

\$172,916,967.00, plus accrued interest on that amount of 1.375% per annum commencing on December 11, 2012 and continuing and including the day payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Defendants shall pay to the United States the sum of \$137,700,171.51, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Defendants shall pay to the Medicaid Participating States the sum of \$35,216,795.49 plus accrued interest as set forth above ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 30 day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Defendants.

(c) Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Defendants and the State Team have agreed, or in a form otherwise agreed to by Defendants and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to Endo's attorneys within 30 days of receiving this Agreement. If this condition is not satisfied within 30 days, Endo's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Endo and the State Team to extend the 30 day period.

(d) The total portion of the amount paid by Defendants in settlement for the Covered Conduct for the State is \$1,558,486.86, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$564,055.36, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 30 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendants absent written agreement between counsel for Defendants and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Endo in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Action

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon receipt by

the State of its share of the Medicaid State Settlement Amount, the State agrees to release Endo, its predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively (collectively, the "Endo Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including any Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;

- (f) any liability based upon obligations created by this Agreement;
- (g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;
- (h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by Endo;
- (i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- (j) any liability based on a failure to deliver goods or services due.

5. In consideration of the obligations of Defendants set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") that Defendants has entered into with the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") in connection with this matter, and conditioned on receipt by the State of its share of the State Medicaid Settlement Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against Defendants for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against Defendants in the event that Defendants are excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Defendants waive and shall not assert any defenses they may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth

Amendment of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, Defendants waive and discharge the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Defendants have asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Defendants must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and Defendants agree not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

9. Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

10. Defendants expressly warrant that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and

548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument, the Parties do not release any liability against any other person or entity.

14. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

15. In addition to all other payments and responsibilities under this Agreement, Defendants agree to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

16. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

17. The undersigned Defendants' signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

18. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

20. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF NORTH CAROLINA

By: Charles H. Hobgood

Dated: 1/30/2014

CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

By: Sandy Terrell

Dated: 1/27/14

SANDY TERRELL, Acting Director
Division of Medical Assistance

**ENDO HEALTH SOLUTIONS INC.
ENDO PHARMACEUTICALS INC.**

By: ULL Dated: 2/19/14

**Rajiv De Silva
President and CEO**

By: [Signature] Dated: 2/19/14

**Counsel to Endo Health Solutions Inc.
Endo Pharmaceuticals Inc.**