

State of North Carolina

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January 3, 2013

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 Harry Brown
Senator Thom Goolsby
Representative James Boles, Jr.
Representative Leo Daughtry
Representative Pat Hurley
Representative Shirley B. Randleman
Co-Chairs, Appropriations Subcommittees 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 Boehringer
Ingelheim Pharmaceuticals, Inc. (Aggrenox, Atrovent, Combivent &
Micardis)

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.

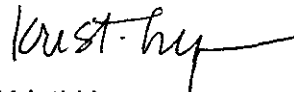
A Settlement Agreement has been executed between Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") and the State of North Carolina. BIPI is a Delaware corporation headquartered in Ridgefield, Connecticut. BIPI developed, distributed, marketed and sold pharmaceutical products in the United States, including drugs sold under the trade names Aggrenox, Atrovent, Combivent and Micardis.

The settlement resolves allegations that from January 1, 2000 through December 31, 2008, BIPI improperly marketed Aggrenox, Combivent and Micardis for uses not approved by the FDA, and paid illegal remuneration to cause the off-label promotion and prescription of Aggrenox, Atrovent, Combivent and Micardis.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$1,970,099.84. Of that amount the federal government will receive \$1,200,980.74 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government will receive \$164,908.35 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$294,363.15 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 \$286,242.44 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 \$23,605.16 for investigative costs and costs of collection.

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

Very truly yours,



Kristi Hyman
Chief of Staff

KH:ng

cc: Kristine Leggett, NCGA Fiscal Research Division
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 Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), hereinafter collectively referred to as "the Parties".

II. PREAMBLE

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

A. At all relevant times, BIPI, a Delaware corporation headquartered in Ridgefield, Connecticut, developed, distributed, marketed and sold pharmaceutical products in the United States, including the drugs sold under the trade names Aggrenox®, Atrovent®, Combivent® and Micardis®.

B. *Qui Tam* Action

On or about February 17, 2005, Robert Heiden ("Relator") filed a *qui tam* action in the United States District Court for the District of Maryland captioned United States of America and the states of California, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, Tennessee, Texas, Virginia and the District of Columbia, ex rel. v. Boehringer Ingelheim et al., Civil Action No. JFM-05-484 (D. Md.). On or about May 16, 2005, the Relator filed his First Amended Complaint adding additional counts. On or about November 14, 2007, Relator filed a Second Amended Complaint adding additional counts under the false claims statutes for the states of Georgia, Indiana, Louisiana, Montana, New Hampshire, New York and Oklahoma. On or about November 3, 2010, Relator filed his Fourth Amended Complaint adding

Medicaid program and on which the State's Medicaid program relied in making formulary and prior authorization decisions. BIPI represented to the State's Medicaid program that Atrovent® was a more cost-effective treatment than its competitors based upon its labeled dosing information (2 puffs every 4 hours, not to exceed 12 puffs per 24 hours) despite the fact that BIPI marketed Atrovent® at doses in excess of its label (more than 12 puffs per 24 hours);

(iii) Combivent®: During the period of January 1, 2000 to December 31, 2005, BIPI knowingly promoted the sale of Combivent® for use prior to another bronchodilator in treating Chronic Obstructive Pulmonary Disease, a use which was not approved by the FDA and which was not a medically-accepted indication (as defined in 42 U.S.C. § 1396r-8(k)(6)), and not covered by the State's Medicaid program, and BIPI knowingly promoted the sale and use of Combivent® at dosages that exceeded those covered by the State's Medicaid program;

(iv) Micardis®: During the time period of January 1, 2000 to December 31, 2008, BIPI knowingly promoted the sale and use of Micardis® for uses for which Micardis® had not been approved by the FDA, including treatment of early diabetic kidney disease. Certain of these uses were not medically-accepted indications and were not covered by the State's Medicaid program;

(v) Programs: During the time period of January 1, 2002 to December 31, 2008, BIPI (a) offered and provided services and other things of value to health care professionals for participating in programs such as the Ambulatory Blood Pressure Monitoring program and the Inspiring Improvement program to induce them to promote and prescribe Aggrenox®, Atrovent®, Combivent® and Micardis®, and these

prescriptions were reimbursed by the State's Medicaid program; and (b) offered and provided remuneration to health care professionals for participating in programs such as certain advisory boards, speakers' training programs, speaker programs, and consultant programs to induce them to promote and prescribe Aggrenox®, Atrovent®, Combivent® and Micardis®, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and that these prescriptions were reimbursed by the State's Medicaid program.

As a result of the foregoing conduct described in subparagraphs (i)-(v), BIPi knowingly caused the submission of false and fraudulent claims for Aggrenox®, Atrovent®, Combivent® and Micardis® to the State's Medicaid program.

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by BIPi nor a concession by the State that its allegations are not well founded. BIPi expressly denies the allegations of the United States and the State as set forth herein, in the Federal Settlement Agreement and in the Civil Action and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by BIPi. The allegations that are described herein are not intended to constitute evidence admissible in a court of law.

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. Pursuant to the Federal Settlement Agreement, BIPJ agrees to pay to the United States and the Medicaid Participating States (as defined in Paragraph III.1. (c)), collectively, the sum of \$95,000,000.00, plus accrued interest on that amount of 1.625% per annum commencing on October 31, 2011, and continuing and including the day before 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) BIPJ shall pay to the United States the sum of \$78,455,048.00, plus accrued interest on that amount at the rate of 1.625% per annum commencing on October 31, 2011, ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States Attorney's Office for the District of Maryland no later than seven (7) business days

after the Federal Settlement Agreement is fully executed by the parties to that Agreement and delivered to counsel for BIPI.

(b) BIPI shall pay to the Medicaid Participating States (as defined in Paragraph III.1. (c)), the sum of \$16,544,952.00, plus accrued interest ("Medicaid State Settlement Amount") subject to the non-participating state deduction provision of sub-paragraph (d) below, no later than ten (10) business days after the expiration of the 60 day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account ("NY State Account") pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for BIPI. After making the Medicaid State Settlement Amount payment to the NY State Account, BIPI shall have no continuing obligations with respect to payment of the aggregate amount to the Medicaid Participating States.

(c) BIPI shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which BIPI and the State Team have agreed or in a form otherwise agreed to by BIPI and an individual State. The State shall constitute a Medicaid Participating State in this Settlement Agreement provided this Settlement Agreement is fully executed by the State and delivered to BIPI's attorneys within the period of 60 days immediately following receipt of this Settlement Agreement. If this condition is not satisfied within 60 days, BIPI's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for BIPI and the State Team to extend the 60 day period.

(d) The total portion of the Settlement Amount paid by BIPI in settlement for the Covered Conduct for the State is \$1,961,979.13, consisting of a portion paid to the State under this Agreement and another portion paid to the Federal Government as part of the Federal Settlement Agreement. The individual portion of the Medicaid State Settlement Amount allocated to the State under this Agreement is the sum of \$760,998.40, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within the period of 60 days immediately following receipt of this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by BIPI absent written agreement between counsel for BIPI and the State Team to extend the time period for executing this Agreement.

(e) BIPI may, at its sole discretion, waive any rights that it has reserved with respect to payment of any of the State Amounts as defined in Paragraph III.1(d).

2. (a) The State agrees to dismiss with prejudice any lawsuit, including any supplemental state law claims asserted in the Civil Action, currently pending against the BIPI Released Entities (as defined below) in any State or Federal Court asserting allegations or claims as a result of the Covered Conduct in which the State has intervened or which the State has the authority to dismiss, except to the extent that any such lawsuits include claims for non-Covered Conduct.

(b) Contingent upon the receipt of their respective State Amounts, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the relators the amount of \$164,908.35, plus applicable interest. This amount is to be paid

through the State Team and has been addressed via a side letter with the Plaintiff-Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, and in consideration of the obligations of BIPi set forth in this Agreement, conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, and subject to Paragraph 11 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the State on behalf of itself, and its officers, agents, agencies, political subdivisions and departments to the extent authorized by law, agrees to release BIPi, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, and assigns, and their current and former directors, officers and employees, (collectively, the "BIPi Released Entities"), from any civil or administrative monetary cause of action that the State, its officers, agents, agencies, political subdivisions and departments to the extent authorized by law have or may have 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) any applicable mandatory exclusions from the State's Medicaid program;

(h) any expressed or implied warranty claims or other liability for defective or deficient products and services provided by BIPI;

(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 items or services due.

5. In consideration of the obligations of BIPI set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") that BIPI 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, except as reserved in Paragraph 4 above and subject to Paragraph 11 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment

under this Agreement), the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action or claim seeking exclusion from the State's Medicaid program against the BIPI Released Entities for the Covered Conduct. The State's Medicaid Fraud Control Unit further agrees to refrain from recommending, causing or attempting any administrative action or sanction, including debarment, by any other government agency of the State for the Covered Conduct. Nothing in this Agreement precludes the State from taking action against BIPI Released Entities in the event that any BIPI Released Entity is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. BIPI waives and shall not assert any defenses it 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 to 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, BIPI waives and discharges 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 BIPI 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 BIPI 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, if applicable, BIPI agrees 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. BIPI shall not seek payment for any of the claims for reimbursement to Medicaid covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

10. BIPI expressly warrants 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 Medicaid State Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to BIPI within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do in fact, constitute such a contemporaneous exchange.

11. In the event BIPI commences, or another party commences, within 91 days of the Effective Date of this Agreement or any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of BIPI's debts,

or seeking to adjudicate BIPI as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for BIPI or for all or any substantial part of BIPI's assets, BIPI agrees as follows, to the extent consistent with applicable law:

(a) BIPI obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and BIPI shall not argue or otherwise take the position in any such case, proceeding or action that: (i) BIPI's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) BIPI was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the State hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to BIPI.

(b) If BIPI's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the State, at its sole option, may rescind the releases provided in this Agreement, and bring any civil and/or administrative action or proceeding against BIPI for the liability that would otherwise be covered by the releases provided in this Agreement. If the State chooses to do so, BIPI agrees that for purposes only of any actions or proceedings referenced in this first clause of this Paragraph, any such actions or proceedings brought by the State (including any proceedings to exclude BIPI from participation in the State's Medicaid program) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that BIPI shall not argue or otherwise contend that the State's actions or proceedings are subject to an automatic stay; BIPI shall

not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative actions or proceedings which are brought by the State within 90 calendar days of written notification to BIPI that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before February 17, 2005 and the State has a valid demand against BIPI in the amount of its share of the Medicaid State Settlement Amount plus applicable multipliers and penalties and it may pursue its demand *inter alia*, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action or proceeding; and BIPI acknowledges that its obligations set forth in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

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

13. BIPI agrees to cooperate fully and truthfully, as set forth below, with any State investigation by the State's Medicaid Fraud Control Unit of individuals or entities not released in this Agreement relating to the Covered Conduct. Upon reasonable notice, BIPI shall encourage, and agree not to impair, the cooperation of its directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of BIPI.

14. 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.

15. 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.

16. 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.

17. In addition to all other payments and responsibilities under this Agreement, BIPi agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees. BIPi 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.

18. This Agreement is governed by the laws of the State, except that 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.

19. The undersigned BIPi 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.

20. 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.

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

22. This Settlement 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.

23. 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. Hobbgood

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

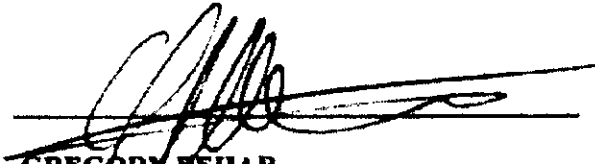
Dated: 8/6/2012

By: Michael Watson

MICHAEL WATSON
Director, Division of Medical Assistance

Dated: 7-26-12

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

BY:  DATED: 10/20/12
GREGORY BEHAR
President and Chief Executive Officer
Boehringer Ingelheim Pharmaceuticals, Inc.

BY: _____ DATED: _____

J. SEDWICK SOLLERS III
MARK A. JENSEN
King and Spalding LLP
Counsel for Boehringer Ingelheim Pharmaceuticals, Inc.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

BY: _____

DATED: _____

GREGORY BEHAR
President and Chief Executive Officer
Boehringer Ingelheim Pharmaceuticals, Inc.

BY:  _____

DATED: 10-22-12

J. SEDWICK SOLLERS III
MARK A. JENSEN
King and Spalding LLP
Counsel for Boehringer Ingelheim Pharmaceuticals, Inc.