



State of North Carolina

ROY COOPER
ATTORNEY GENERAL

Department of Justice
PO Box 629
Raleigh, North Carolina
27602

Phone: (919) 716-6400
Fax: (919) 716-6750

November 12, 2014

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 Shirley Randleman
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 Dr. Francis Bald
G.S. §114-2.5; Report on Settlement Agreement for Omnicare, Inc.
G.S. §114-2.5; Report on Settlement Agreement for Organon USA,
Inc. - Remeron and Remeron SolTab
G.S. §114-2.5; Report on Settlement Agreement for Organon USA,
Inc. - Tice BCG, NuvaRing, Cyclessa, Mircette, and Desogen
G.S. §114-2.5; Report on Settlement Agreement for Shire
Pharmaceuticals

Dear Members:

G.S. §114-2.5 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 matters. 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.

Dr. Francis Bald

A Settlement Agreement has been executed between Dr. Francis Bald and the State of North Carolina. Dr. Francis Bald is licensed to practice dentistry in the state of North Carolina. The settlement resolves allegations that from January 2, 2010 through December 30, 2011, Dr. Bald billed for services not rendered.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$286,809.20. Of that amount the federal government will receive \$186,540.70 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$97,079.96 as restitution. Pursuant to G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$3,188.54 for investigative costs.

Omnicare, Inc.

A Settlement Agreement has been executed between Omnicare, Inc. and the State of North Carolina. Omnicare is an institutional pharmacy that provides pharmacy goods and services to residents of nursing homes and other long-term care facilities. The settlement resolves allegations that from January 19, 2004 through June 30, 2012, Omnicare offered and paid remuneration to skilled nursing facilities through (a) discounted per diem pricing for drugs provided to Medicare Part A patients; (b) prompt pay discounts; (c) free drugs; and (d) discounted fee-for-service pricing for drugs provided to Medicare Part A patients, to induce the referral of the remaining pharmacy business to Omnicare, including for drugs provided to patients covered by Medicaid.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$216,765.12. Of that amount the federal government will receive \$131,352.46 for 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 \$23,061.42 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$30,184.24 as restitution. 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 \$30,184.24 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 \$1,982.76 for investigative costs and costs of collection.

Organon USA, Inc. - Remeron and Remeron SolTab

A Settlement Agreement has been executed between Organon USA, Inc. and the State of North Carolina. Organon USA, Inc. is a New Jersey corporation, as well as Organon Pharmaceuticals USA, Inc., and Organon International, Inc., both Delaware corporations that were merged into Organon USA, Inc. At all relevant times, Organon distributed, marketed and/or sold pharmaceutical products in the United States under the trade names of Remeron and Remeron SolTab. The settlement resolves

allegations that from January 1, 1999 through December 31, 2006, Organon knowingly manipulated and failed to report its true Best Price to CMS for the sale of its drugs Remeron and Remeron SolTab. This settlement also resolves allegations that Organon provided kickbacks to Long Term Care Pharmacy providers and off-label marketed its drugs Remeron and Remeron SolTab.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$297,230.19. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$83,224.45 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$207,200.36 as restitution. Pursuant to G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$6,805.38 for investigative costs.

Organon USA, Inc.- Tice BCG, NuvaRing, Cyclessa, Mircette, and Desogen

A Settlement Agreement has been executed between Organon USA, Inc. and the State of North Carolina. At all relevant times, Organon distributed, marketed and/or sold pharmaceutical products in the United States under the trade names of Tice BCG, NuvaRing, Cyclessa, Mircette, and Desogen. The settlement resolves allegations that from January 1, 1999 through September 30, 2007, Organon knowingly manipulated and failed to report its true Best Price to CMS for the sale of its contraceptive drugs NuvaRing, Mircette, Desogen and Cyclessa. This settlement also resolves allegations that Organon reported inflated Average Wholesale Price ("AWP") information for its product Tice BCG and marketed the difference between acquisition cost and AWP in promoting the product.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$699,129.86. Of that amount the federal government will receive \$448,062.71 for 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 \$70,298.80 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$175,019.92 as restitution. Pursuant to G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$5,748.43 for investigative costs.

Shire Pharmaceuticals

A Settlement Agreement has been executed between Shire Pharmaceuticals and the State of North Carolina. Shire is a Delaware corporation with its principal place of business in Wayne, Pennsylvania. At all relevant times, Shire distributed, marketed and sold drugs in the United States, including Adderall XR, Vyvanse, Daytrana, Lialda, and Pentasa. The settlement resolves allegations that from January 2004 through September 2010, Shire off-label marketed its drugs Adderall XR, Vyvanse, Datrana, Lialda, and Pentasa.

Under the terms of North Carolina's settlement, the State of North Carolina will

recover \$2,803,225.89. Of that amount the federal government will receive \$1,821,071.15 for 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 \$181,836.03 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$369,022.11 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 \$406,319.14 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 \$24,977.46 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 Jones
Chief of Staff

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

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is entered into between the State of North Carolina, by and through the North Carolina Attorney General ("State"), and Francis A. Bald, D.D.S.; Dr. Francis A. Bald & Associates, P.A., a North Carolina Corporation; and Northeastern North Carolina Oral Maxillo-Facial Surgery. (collectively "Dr. Bald"), (each of the above hereafter collectively referred to as "the Parties") by and through their authorized representatives.

I. PREAMBLE

As a preamble to this Settlement Agreement ("Agreement"), the Parties agree to the following:

A. Dr. Bald is licensed to practice dentistry in the state of North Carolina and has participated as a health care provider in the North Carolina Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v ("Medicaid").

B. The State contends that, in its capacity as a health care provider, Dr. Bald knowingly submitted false claims for approval to the Medicaid program, or made, used, or caused to be made or used a false record or statement material to a false or fraudulent claim for payment made to the Medicaid program.

C. On or about September 5, 2013, Dr. Bald entered a plea of guilty pursuant to State Misdemeanor Criminal Charges (the "Plea Agreement") to two separate counts of Medicaid Assistance Provider Fraud Scheme or Artifice (108A-63a) and was ordered to pay restitution to the North Carolina Fund for Medical Assistance in the amount of \$114,723.68.

D. The State contends that it has civil and administrative claims against Dr. Bald under North Carolina statutes and/or common law doctrines for submitting claims to the Medicaid program for certain services during the period from January 2, 2010 through December 30, 2011 pertaining to multiple North Carolina Medicaid recipients and CPT Codes D8221, D023, and D9230, respectively, ("Covered Conduct"), for which services were billed to Medicaid but not in fact rendered, and to which Dr. Bald pled guilty to as set forth above.

E. The parties have previously executed a Confession of Judgment and Escrow Agreement arising from the identical claims of the State. This document and the Confession of Judgment and Escrow Agreement are to be construed together as a single settlement agreement with each party being entitled to the benefits and responsible for the obligations contained in all instruments.

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

II. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Dr. Bald agrees to pay the State of North Carolina the sum of Two Hundred Eighty Six Thousand Eight Hundred Nine Dollars and Twenty Cents (\$286,809.20) ("Settlement Amount") as follows: Dr. Bald agrees to deliver a certified or cashier's

check in the amount of \$500.00 made payable to the North Carolina Fund for Medical Assistance to the North Carolina Department of Justice, Medicaid Investigations Division, 5505 Creedmoor Road, Suite 300, Raleigh, NC 27612, on or before August 25, 2014. Thereafter, Dr. Bald agrees to deliver a certified or cashier's check made payable to the North Carolina Fund for Medical Assistance to the North Carolina Department of Justice at the address provided above, in the amount of \$500.00, continuing on or about the 1st day of each month thereafter until January 1, 2015. Thereafter, Bald shall pay the sum of \$1,000.00 on the 1st day of each month until July 1, 2015, at which time the payments shall increase to \$1,500.00 per month, due and payable on or about the 1st day of each month until January 1, 2016. Thereafter, the unpaid balance shall be due and payable. Provided, however, prior to recording the Confession of Judgment, the parties shall discuss a continuation of installment payments and an extension of this escrow agreement. Such discussions shall be in good faith and with a genuine attempt to resolve outstanding indebtedness taking into account Bald's financial condition, licensure, Medicaid and Medicare participation eligibility, assets, and the like.

2. Subject to the exceptions in this Agreement, in consideration of the obligations of Dr. Bald set forth in this Agreement, and conditioned upon payment in full of the Settlement Amount, the State releases and discharges Dr. Bald, its shareholders, and its officers, directors, and managers, from any civil monetary claims and administrative penalties the State has or may have under North Carolina statutes and/or common law doctrines for the Covered Conduct.

3. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement, are the following:

- a. Any claims arising under any North Carolina revenue laws or regulations;
- b. Any liability to North Carolina for any conduct other than the Covered Conduct;
- c. Any claims based upon obligations created by this Agreement;
- d. Any claims for defective or deficient medical services, including claims as may be brought under North Carolina consumer protection statutes; and
- e. Any claims against any entities or persons other than Dr. Bald and its shareholders, officers, or managers.

4. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the settlement amount for purposes of the Internal Revenue Code or State revenue laws.

5. In the event that Dr. Bald breaches this Agreement, Dr. Bald expressly agrees not to plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, except to the extent that these defenses were available on or before the date this agreement is executed, to any civil claims (a) that are filed by the State within 120 days of written notification to Dr. Bald that this Agreement has been breached and the releases herein have been rescinded and (b) that relate to the Covered Conduct.

6. Dr. Bald fully and finally releases the State, its agencies and employees, from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Dr. Bald could have asserted or may assert in the future against the State, its agencies and employees, related to the Covered Conduct and the investigation of the State of the Covered Conduct.

7. Dr. Bald agrees that it will not amend or resubmit any claims already submitted to the Medicaid program for the Covered Conduct unless requested to do so by the Medicaid Program.

8. Dr. Bald agrees that all costs incurred by or on behalf of himself and his corporation in connection with: (1) the matters covered by this Agreement, (2) the State's audit and investigation of the Covered Conduct, (3) Dr. Bald's investigation, defense, and corrective actions undertaken in response to the State's audit and investigation of the Covered Conduct, including attorney's fees, (4) the negotiation of this Agreement, and (5) the payment made pursuant to this Agreement, are unallowable costs on contracts with the State and United States and for Medicaid and Medicare reimbursement purposes (hereinafter, "unallowable costs"). Dr. Bald represents and agrees that these unallowable costs have been and will be separately estimated and accounted for by Dr. Bald, and that Dr. Bald has not and will not charge these unallowable costs directly or indirectly to any contracts with the State, the United States, or any state Medicaid Program, or seek payment for unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Dr. Bald to the Medicaid Program, Medicare Program or to any other State or Federal program.

9. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

10. Dr. Bald agrees that he will not seek payment for any of the health care claims covered by this Agreement from any health care recipients or their family members, sponsors, heirs, guardians, trustees, agents, attorneys-in-fact, or private insurance carriers. Dr. Bald waives any causes of action against these recipients or their

family members, sponsors, heirs, guardians, trustees, agents, attorneys-in-fact, or private insurance carriers based upon the claims for payment covered by this Agreement.

However, this provision is not intended to extend to any Medicaid billing company which Dr. Bald relied upon in its billing practices which are the subject of this Agreement.

11. The Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (1) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Dr. Bald, within the meaning of 11 U.S.C. § 547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

12. In the event that Dr. Bald commences, or a third party commences, within 91 days of any payment under this Agreement, any case, proceeding, or other action (a) under any law relating to bankruptcy, insolvency, reorganization or relief of debtors, seeking to have any order for relief of Dr. Bald's debts, or seeking to adjudicate Dr. Bald as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Dr. Bald or for all or any substantial part of Dr. Bald's assets, Dr. Bald agrees as follows:

a. Dr. Bald's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Dr. Bald will not argue or otherwise take the position in any such case, proceeding or action that (1) Dr. Bald's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) Dr. Bald 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 (3) the mutual promises, covenants and obligations set forth in this

Agreement do not constitute a contemporaneous exchange for new value given to Dr. Bald.

b. In the event that Dr. Bald's obligations hereunder are avoided pursuant to 11 U.S.C. § 547, the State, at its sole option, may rescind the releases in this Agreement, and bring any civil claim, action or proceeding against Dr. Bald for the claims that would otherwise be covered by the release provided herein. If the State chooses to do so under the provisions of this subparagraph, but in no other event, Dr. Bald agrees that (1) any such claims, actions or proceedings brought by the State 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 Dr. Bald will not argue or otherwise contend that the State's claims, actions or proceedings are subject to an automatic stay; (2) that the State has a valid claim against Dr. Bald in the amount of at least \$286,809.20 under State statutes and/or common law doctrines, and the State may pursue its claim in any case, action, or proceeding. The statement contained herein regarding the State's "valid claim" is solely for the purposes of this subpart and, except in the event the State brings an action under the provisions of this subparagraph, in no way admits liability on the part of Dr. Bald for the claims of the State, said liability being expressly denied.

c. Dr. Bald acknowledges that its agreements in this paragraph are provided in exchange for valuable consideration provided in this Agreement.

13. The Parties will each bear their own respective legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Dr. Bald represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever and in consultation with legal counsel.

15. This Agreement shall be governed, construed, and enforced by and in accordance with the laws of the State of North Carolina, without regard to its conflict of laws rules, and the Parties agree that the sole and exclusive jurisdiction and sole and exclusive venue for any dispute arising between the Parties under, regarding, or relating to this Agreement will be Superior Court for Wake County, North Carolina.

17. This Agreement, and the aforementioned Confession of Judgment and Escrow Agreement constitutes the complete agreement between the parties and supercedes all prior negotiations, agreements, and understanding with respect thereto. This Agreement may not be amended except by written consent of the Parties.

18. The undersigned individuals signing this Agreement represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties, and that any and all necessary actions (including but not limited to formal corporate Board of Directors' action, resolution, and/or other Board or shareholder authorization) have been taken to fully authorize the execution of this Agreement by the undersigned individuals on behalf of the respective Parties.

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

20. The invalidity, illegality, or unenforceability of any provisions of this Agreement shall not affect the validity, legality, or enforceability of any other provisions of this Agreement, which shall remain in full force and effect.

21. This Agreement is effective on the date of signature of the last signatory to the Agreement and shall become final and binding only upon signing by each of the Parties hereto.

This SETTLEMENT AGREEMENT agreed and executed by the Parties hereto:

THE STATE OF NORTH CAROLINA

10/24/2014
DATE

BY: Charles H. Hobgood
CHARLES H. HOBGOOD
Special Deputy Attorney General
North Carolina Department of Justice
Director, Medicaid Investigations Division
5505 Creedmoor Road, Suite 300
Raleigh, North Carolina 27612

FRANCIS A. BALD, D.D.S.

Oct 7, 2014
DATE

BY: Francis A. Bald
FRANCIS A. BALD, D.D.S. (individually)

DR. FRANCIS A. BALD & ASSOC., P.A.

Oct 7, 2014
DATE

BY: Francis A. Bald
FRANCIS A. BALD, D.D.S.

NORTHEASTERN NORTH CAROLINA ORAL
MAXILLO-FACIAL SURGERY

Oct 7, 2014
DATE

BY: Francis G. Bald
FRANCIS A. BALD., D.D.S.

Oct 24 2014
DATE

BY: Morrison
JOHN S. MORRISON
THE TWIFORD LAW FIRM, P.C.
COUNSEL FOR DEFENDANT(S)

ATTEST:

Secretary
{CORPORATE SEAL}

STATE SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Omnicare, Inc., NCS Healthcare, LLC. and Neighborcare, Inc. (collectively "Omnicare") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Omnicare is an institutional pharmacy that provides pharmacy goods and services to residents of nursing homes and other long-term care facilities. Throughout the period referenced in this Agreement, certain of Omnicare's pharmacy goods and services were reimbursed by government healthcare programs, including Medicare and Medicaid.

B. On January 19, 2010, Relator Donald Gale filed a *qui tam* action in the United States District Court for the Northern District of Ohio (the "Gale Court"), captioned *United States ex rel. Gale v. Omnicare, Inc.*, Civil Action No. 1:10-cv-0127, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Gale Civil Action").

C. On March 4, 2011, Relator Marc Silver filed a *qui tam* action in the United States District Court for the District of New Jersey (the "Silver Court"), captioned *United States, et al. ex rel. Silver v. Omnicare, Inc. et al.*, Civil Action No. 1:11-cv-01326, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and various state False Claims Acts and other laws (the "Silver Civil Action").

D. The Gale Civil Action and the Silver Civil Action are referred to collectively as the Civil Actions. Omnicare has entered into a separate civil settlement agreement (the

"Federal Settlement Agreement") with Relators Gale and Silver and with the United States (as the United States is defined in the Federal Settlement Agreement).

E. The State contends that Omnicare engaged in the following conduct:

During the period from January 19, 2004 through June 30, 2012, Omnicare offered and paid remuneration to skilled nursing facilities through (a) discounted per diem pricing for drugs provided to Medicare Part A patients; (b) prompt pay discounts; (c) free drugs; and (d) discounted fee-for-service pricing for drugs provided to Medicare Part A patients, to induce the referral of the remaining pharmacy business to Omnicare, including for drugs provided to patients covered by Medicare Part D and the state Medicaid programs, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and provided per diem or fee-for-service pricing in violation of "most favored nation"/"most favored customer" pricing. The State further contends that Omnicare, during the time period of January 19, 2004 through December 31, 2013 and as a result of the foregoing conduct, submitted or caused to be submitted false claims that were reimbursed by federal healthcare programs, including through Medicare Part D reimbursements and the state Medicaid programs, in violation of the federal False Claims Act, State False Claims Acts and other laws.

This conduct is hereinafter referred to as the "State Covered Conduct"

F. The State Covered Conduct specifically does not include claims alleged under the federal and state False Claims Acts in the Third Amended Complaint filed in *United States, et al. ex rel. Ruscher v. Omnicare, Inc., et al.*, Civil Action No. 08-3396, pending in the Southern District of Texas.

G. The State contends that it has certain civil and administrative causes of action against Omnicare for engaging in the State Covered Conduct.

H. This Settlement Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Omnicare, nor a confession by the State that its allegations are not well founded. Omnicare expressly denies the allegations set

forth herein and in the Silver Civil Action. Neither this Agreement or its execution, nor the performance of any obligations arising 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 on the merits of the dispute by any party to this Agreement.

I. 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.

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. Omnicare agrees to pay to the Medicaid Participating States (as defined in Paragraph 1(b) below), collectively, the sum of EIGHT MILLION TWO HUNDRED AND FORTY THOUSAND DOLLARS (\$8,240,000.00) (the "Medicaid State Settlement Amount"). The debt shall forever be discharged by payment to the Medicaid Participating States, under the following terms and conditions:

(a) The Medicaid 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 Omnicare. Unless otherwise agreed to in writing by Omnicare and the State Team, Omnicare shall pay the Medicaid State Settlement Amount (as may be reduced consistent with Paragraph 1(c) below) within seven

(7) days of receipt of the executed State Settlement Agreement (in a form agreed to by Omnicare) by every Medicaid Participating State, provided that the State Team has provided written notice to Omnicare of receipt of the Stipulation of Dismissal with Prejudice of All State Law Claims in the Silver Action which has been executed by Relator Silver and Silver's counsel, and which shall be tendered to Omnicare within three (3) days of payment of the Medicaid State Settlement Amount.

(b) Omnicare shall execute a Settlement Agreement with any State that executes such an Agreement in the form to which Omnicare and the State Team have agreed, or in a form otherwise agreed to by Omnicare and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to Omnicare's attorneys within 45 days of receiving this Agreement. If this condition is not satisfied within 45 days, Omnicare's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Omnicare and the State Team to extend the 45-day period.

(c) The total portion of the amount paid by Omnicare in settlement for the State Covered Conduct for the State is \$85,412.66 (the "State Amount"). If the State does not execute this Agreement within 45 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall be retained by Omnicare, absent written agreement between counsel for Omnicare and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any claims currently pending against Omnicare in State or Federal Courts for the State Covered Conduct and, if named in the Silver Civil Action, consents to the dismissal with prejudice of the Silver Civil Action

and executes Exhibit A attached. Contingent upon the receipt of its State Amount, the State, if properly served with the Silver Civil Action and liable to pay a Relator's share, agrees to pay, as soon as feasible after such receipt, such amount as has been or will be negotiated with the Relator in the Silver Civil Action, which shall be set forth in a side letter issued to and executed by the Relator in the Silver Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Omnicare set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release Omnicare, 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 "Omnicare 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's Medicaid Program as a result of the State 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 Omnicare 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 State Covered Conduct;

(e) any liability which may be asserted on behalf of any other payors or insurers, including those claims by other payors or insurers 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 express or implied warranty claims or other claims for defective or deficient products and services provided by Omnicare;

(i) any liability for personal injury or property damage or for other consequential damages arising from the State Covered Conduct; or

(j) any liability based on a failure to deliver goods or services due.

5. Omnicare waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the State 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. Nothing in this Agreement constitutes an agreement by the State concerning the characterization the amount paid hereunder for purposes of any revenue code.

6. In consideration of the obligations of the State set forth in this Agreement, Omnicare 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 Omnicare has 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 State Covered Conduct.

7. The amount that Omnicare must pay to the State pursuant to Paragraph 1(c) 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 State Covered Conduct; and Omnicare 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 State Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

8. Omnicare 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.

9. Omnicare expressly warrants that it has reviewed its financial condition and that it is currently solvent, and that payment of the Medicaid State Settlement Amount described in Paragraph 1 shall not render Omnicare insolvent.

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

11. Except for the State Team expenses and costs identified in Paragraph 15 below, 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.

12. 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.

13. This Agreement is governed by the laws of the State 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.

14. The undersigned Omnicare 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.

15. In addition to all other payments and responsibilities under this Agreement, Omnicare agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Omnicare 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. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles and electronic copies of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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

18. 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.

19. 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

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

Dated: 7/28/2014

By: [Signature]

ROBIN G. CUMMINGS, M.D., Director
Division of Medical Assistance

Dated: 7/24/14

OMNICARE, INC.

By: Alexander M. Kayne Dated: 8/26/14

Alexander Kayne
General Counsel

By: _____ Dated: _____

J. Andrew Jackson
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001.2113
(202) 879-3939

Tina M. Tabacchi
JONES DAY
77 W. Wacker Dr.
Suite 3500
Chicago, IL 60601
(312) 782-3939

Counsel to Omnicare, Inc.

OMNICARE, INC.

By: _____ Dated: _____

Alexander Kayne
General Counsel

By:  _____ Dated: 8.27.14

Tina M. Tabacchi
JONES DAY
77 W. Wacker Dr.
Suite 3500
Chicago, IL 60601
(312) 782-3939

J. Andrew Jackson
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001.2113
(202) 879-3939

Counsel to Omnicare, Inc.

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State"), Organon, as defined below, and Akzo Nobel N.V. 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, Organon USA Inc., a New Jersey corporation, as well as Organon Pharmaceuticals USA Inc. LLC, and Organon International, Inc., both Delaware corporations that were merged into Organon USA Inc. (all three companies collectively referred to as the "Organon Operating Entities"), were wholly owned subsidiaries of Organon Biosciences N.V, which was, in turn, wholly owned by Akzo Nobel N.V. ("Akzo Nobel"), a Dutch corporation. At all relevant times, the Organon Operating Entities distributed, marketed and/or sold pharmaceutical products in the United States under the trade names of Remeron and Remeron SolTab that were paid for under the State's Medicaid plan. In 2007, Organon Biosciences N.V. and the Organon Operating Entities were acquired by Schering-Plough Corporation, a New Jersey corporation engaged in the manufacture and sale of pharmaceutical products. Schering - Plough Corporation combined with Merck & Co., Inc., in 2009 (hereinafter, the foregoing entities except Akzo Nobel shall be collectively referred to as "Organon").

B. On September 13, 2007, James Banigan and Richard Templin ("Relators") filed a *qui tam* action in the United States District Court for the Southern District of Texas, Houston Division, captioned *United States of America et al., ex rel. James Banigan and Richard Templin v. Organon USA, Inc., et al.*, Civil Action No. H-07-2953. The case was transferred to the United States District Court for the District of Massachusetts under Civil Action No. 07-12153, and the Relators filed their Third Amended Complaint on March 25, 2011 (hereinafter, the "Civil Action").

C. On June 1, 2012, the Court dismissed all the claims asserted by Relators on behalf of the United States against Organon. Therefore, the United States is not a party to the settlement and will not be entering into a settlement agreement with Organon and/or Akzo Nobel.

D. The State contends that the Organon Operating Entities caused claims for payment to be submitted to the State's Medicaid Program and submitted or caused to be submitted to the Centers for Medicare and Medicaid Services ("CMS") certain reported prices for Remeron and Remeron SolTab pursuant to the Federal Medicaid Program (see 42 U.S.C. §§ 1396-1396v).

E. At all relevant times, the Organon Operating Entities participated in the Medicaid Drug Rebate Program, 42 U.S.C. 1396r-8, which is part of the Federal Medicaid Program. Pursuant to the Medicaid Drug Rebate Program, the Organon Operating Entities entered into national rebate agreements with the United States Department of Health and Human Services ("HHS") and the Organon Operating Entities' covered outpatient drugs were covered by the State's Medicaid plan. Under the Medicaid Drug Rebate Program and the rebate agreements with HHS, the Organon Operating

Entities agreed: (i) to report quarterly to CMS their Average Manufacturer Price ("AMP") for their covered outpatient drugs, as defined by 42 U.S.C. § 1396r-8(k)(1) and their "Best Price" as defined by 42 U.S.C. § 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the State. For single source and innovator multiple source covered outpatient drugs, the quarterly rebates are based on the product of (a) the total number of units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the State, and (b) the greater of the difference between the AMP and the Best Price, or the minimum rebate percentage of AMP, as further described in 42 U.S.C. § 1396r-8(c)(1).

F. Under 42 U.S.C. § 1396r-8(c)(1)(C)(ii), the term "Best Price": (i) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (ii) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (iii) shall not take into account prices that are "merely nominal in amount." Under the rebate agreement, the Best Price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized for that quarter.

G. Under the rebate agreement, a "nominal price" is, for purposes of excluding prices from the Best Price calculation, any price less than 10% of the AMP in the same quarter for which the AMP is computed.

H. The State contends that it has certain civil and administrative causes of action against Organon and Akzo Nobel for engaging in the following conduct (the "Covered Conduct") alleged in the Civil Action:

During the period from January 1, 1999 through December 31, 2006:

- (1) Organon knowingly manipulated and failed to report its true Best Price to CMS for the sale of its drugs Remeron and Remeron SolTab, in that Organon (i) did not include rebates, market share discounts and other improper inducements and remuneration in its Average Manufacturer Price calculations and reporting requirements; (ii) failed to ensure an accurate list of 340B entities that would be excluded from Best Price reporting requirements and ultimately sold these drugs to ineligible entities; and (iii) mischaracterized Remeron transactions as nominal price sales and excluded those sales from Best Price reporting obligations when they were, in fact, not nominal because the sales were more than 10% of the AMP or were conditioned upon other purchase requirements of Remeron or Remeron SolTab. As a result of the conduct alleged above, Organon knowingly reported false Best Prices and thereby underpaid quarterly rebates owed under its rebate obligations with the State Medicaid Program for Remeron and Remeron SolTab;

During the period from January 1, 1999 through December 31, 2005:

- (2) Organon knowingly provided kickbacks to Long Term Care Pharmacy providers including Omnicare, PharMerica, NeighborCare, NCS Healthcare, American Pharmaceutical Services, and Sunscript in the form of market-share discounts and rebates including a "conversion rebate" for switching patients' prescriptions from Remeron to Remeron SolTab and a "therapeutic interchange bonus" for encouraging the utilization of Remeron over other antidepressants;
- (3) Organon knowingly promoted the sale and use of Remeron and Remeron SolTab for conditions that were not approved as safe and effective by the Food and Drug Administration, in that Organon marketed to Long Term Care Pharmacy providers, including Omnicare, PharMerica, NeighborCare, NCS Healthcare, American Pharmaceutical Services and Sunscript, the side-effects of Remeron and Remeron SolTab, including somnolence and increased appetite as possible benefits, and promoted the use of Remeron in children and adolescents for the treatment of depression and attention deficit disorder to induce utilization of Remeron and Remeron SolTab; and
- (4) Organon marketed the spread between the reimbursement rate under the State Medicaid Program and the price paid by Long Term Care Pharmacy providers including Omnicare, PharMerica, NeighborCare, NCS Healthcare, American Pharmaceutical Services, and Sunscript for Remeron and Remeron SolTab, in that Organon knowingly reported false and inflated Average Wholesale Prices ("AWPs") to the State

Medicaid Program, then offered the drugs at a lower cost as a financial inducement to the foregoing Long Term Care Pharmacy providers by increasing the "spread" between the actual cost of the drug to providers vs. the amount that the State Medicaid Program reimburses for that drug, when in fact, Organon knew that the State Medicaid Program would and did use the reported AWP's to reimburse the foregoing Long Term Care Pharmacy Providers for Remeron and Remeron SolTab.

As a result of the foregoing conduct, Organon submitted or caused to be submitted false claims for payment to the State Medicaid Program for Remeron and Remeron SolTab.

I. This agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Organon or Akzo Nobel, nor a concession by the State that its allegations are not well founded. Organon and Akzo Nobel expressly deny the allegations of the State as set forth herein and in the Civil Action.

J. 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. Organon agrees to pay to the Medicaid Participating States (as defined in sub-paragraph (b) below), collectively, the sum of \$12,000,000, (the "Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall constitute a debt due

and owing to the Medicaid Participating States on the Effective Date subject to the terms of this Agreement, including the non-participating state deduction provision of sub-paragraph (c) below. The debt shall forever be discharged by payments to the Medicaid Participating States, under the following terms and conditions:

(a) Organon shall pay to the Medicaid Participating States the Medicaid State Settlement Amount, subject to the non-participating state deduction provision of sub-paragraph (c) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (b) 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 Organon.

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

(c) The total portion of the amount paid by Organon in settlement for the Covered Conduct to the State is \$297,230.19 (the "State Amount"). If the State does not execute this Agreement and deliver it to Organon's attorneys within 60 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Organon absent written agreement between counsel for Organon and the State Team to extend the time period for executing this Agreement.

2. Within fifteen days of receipt of the State Amount, the State, if named in the Civil Action, shall move to or consent to dismiss with prejudice (or otherwise effectuate dismissal with prejudice of) the Civil Action against Organon and Akzo Nobel. Contingent upon receipt by the State of the State Amount, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the Relators the amount of \$83,224.45. This amount is to be paid through the State Team and has been addressed via side letter with the Relators in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Organon set forth in this Agreement, and conditioned upon - receipt by the State of the State Amount, the State (on behalf of itself, its officers, agents, agencies, departments, boards and commissions) hereby fully and finally releases Organon and Akzo Nobel, their predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, shareholders and assigns, and their current and former directors, officers, shareholders and employees, individually and collectively (collectively, the "Organon Released Entities"), from any civil or administrative monetary cause of action that the State has asserted or may have asserted 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 of the Organon 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 Organon;

(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. Organon and Akzo Nobel 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.

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

7. The amount Organon 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 Organon 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.

8. Organon 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.

9. Organon expressly warrants that it has reviewed its financial condition and that it is currently solvent and shall remain solvent following payment of the Medicaid State Settlement Amount described in Paragraph III.1. and in compliance with this Agreement.

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

11. 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.

12. 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.

13. 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.

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

15. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction. 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.

16. The undersigned Organon and Akzo Nobel 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.

17. 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.

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

19. 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.

20. 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
CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

Dated: 9/8/2014

By: Robin G. Cummings
ROBIN G. CUMMINGS, M.D., Director
Division of Medical Assistance

Dated: 8/22/14

NORTH CAROLINA

ORGANON

By:  Dated: 10/15/14

[Name] Bruce N. Kuhlik

[General Counsel] Executive Vice President and General Counsel

Merck & Co., Inc.

By: _____ Dated: _____

Jeffrey L. Handwerker
James W. Cooper
Arnold & Porter LLP
Counsel for Organon

By:  Dated: 10/2/14

John P. McDonald
Locke Lord, LLP
Counsel for Organon

ORGANON

By: _____ Dated: _____

[Name]

[General Counsel]

Merck & Co., Inc.

By: _____

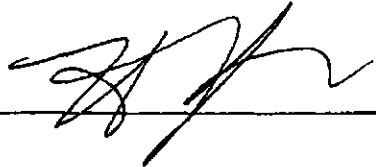
Dated: 10/8/14

Jeffrey L. Handwerker
James W. Cooper
Arnold & Porter LLP
Counsel for Organon

By: _____ Dated: _____

John P. McDonald
Locke Lord, LLP
Counsel for Organon

Akzo Nobel N.V.

By:  _____ Dated: 10/6/14

Counsel for Akzo Nobel N.V.

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Shire Pharmaceuticals LLC ("Shire"), 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, Shire, a Delaware corporation with its principal place of business in Wayne, Pennsylvania, distributed, marketed, and sold drugs in the United States, including Adderall XR, Vyvanse, Daytrana, Lialda, and Pentasa (collectively the "Covered Drugs"). Adderall XR, Vyvanse, and Daytrana are approved by the U.S. Food and Drug Administration ("FDA") for the treatment of attention deficit hyperactivity disorder ("ADHD"). Lialda and Pentasa are FDA approved for the treatment of patients with mildly to moderately active ulcerative colitis.

B. On October 7, 2008, Relator Dr. Gerardo Torres filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States et al. ex rel. Torres v. Shire Specialty Pharmaceuticals et al.*, No. 08-4795 (E.D. Pa.), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3730(b) and various State False Claims Acts. On or about February 14, 2011, Relator Torres filed a Fifth Amended Complaint in the Eastern District of Pennsylvania under the same caption and case number (the "Pennsylvania Action"). On November 6, 2009, Relators Anita Hsieh, Ian Clark, and Kara Harris filed a *qui tam* action in the United States District Court for the Northern District of Illinois captioned *United States et al. ex Shire Settlement Agreement*, Case No. 09-08-01

rel. Hsieh et al. v. Shire PLC et al., No. 09-6994 (N.D. Ill.), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3730(b) and various State False Claims Acts (the "Illinois Action"). The Pennsylvania and Illinois Actions are hereinafter collectively referred to as the "Civil Actions."

C. The Pennsylvania Action names the District of Columbia and the following 29 states: Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Utah, Virginia, and Wisconsin.

D. The Illinois Action names the District of Columbia and the following 22 states: California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

E. Shire will enter into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the "United States."

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

G. The State contends that it has certain civil and administrative causes of action against Shire for engaging in the following conduct as to the Covered Drugs:

Adderall XR. From January 2004 through December 2007, Shire promoted Adderall XR as clinically superior to other ADHD drugs based on its

mechanism of action and its ability to “normalize” patients, despite a lack of clinical data sufficient to support such claims. Shire suggested to doctors that patients on Adderall XR would be moved “into a normalized condition with symptoms that are indistinguishable from [their] non-ADHD peers.” Shire also suggested that treatment with Adderall XR would help prevent several well-known negative consequences of ADHD, such as poor academic performance, loss of employment, criminal behavior, traffic accidents, and sexually transmitted disease. Over that same time period, Shire also promoted Adderall XR for the treatment of conduct disorder, an indication for use which was not approved by the FDA, was not a medically accepted indication (as defined by 42 U.S.C. § 1396r-8(k)(6)), and was not covered by the State’s Medicaid Program. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State’s Medicaid Program.

Vyvanse. From February 2007 through September 2010, Shire made promotional claims suggesting that treatment with Vyvanse would help prevent several well-known negative consequences of ADHD, despite a lack of clinical data sufficient to support such claims. For example, the company implied that use of Vyvanse would reduce the incidence of known consequences of ADHD such as car accidents, divorce, being arrested, and unemployment.

From February 2007 to September 2010, Shire marketed Vyvanse based on a claim that parents preferred Vyvanse to Adderall XR as a treatment for their children, despite a lack of clinical data sufficient to support such a claim.

Over the same time period, certain Shire sales representatives also promoted Vyvanse as “non-abuseable” and/or less abuseable than Adderall XR despite a lack of clinical data sufficient to support such a claim. In support of its claims about Vyvanse’s “abuseability,” certain Shire sales representatives relied on, and incorrectly characterized, studies referenced in the Vyvanse label that compared the drug liking effect (essentially the degree to which patients reported liking a drug) of Vyvanse and an equivalent dose of d-amphetamine (essentially, Adderall *immediate release* – a different drug from Adderall XR). The studies did not conclude that Vyvanse was not abuseable, nor did they offer any comparison of Vyvanse to Adderall XR.

In addition, from February 2007 through September 2010, certain Shire sales representatives and other agents made false and misleading statements about the efficacy and “abuseability” of Vyvanse to state Medicaid formulary committees in order to have the drug included on those states’ formularies and avoid the requirement of prior authorization for Medicaid prescriptions. For example, one Shire medical science liaison made false and misleading statements to a state formulary board that Vyvanse “provides less abuse liability” than “every other long-acting release mechanism” on the market.

Furthermore, from February 2007 through July 2008, certain Shire sales representatives knowingly and improperly made phone calls and drafted letters to Medicaid to assist physicians with the prior authorization process for Medicaid prescriptions of Vyvanse. Medicaid prior authorization programs are designed to ensure that only medically necessary services are provided in a cost-effective manner, and prior authorizations may only be requested by health care providers and their staff. When contacting Medicaid in connection with the prior authorization process, certain Shire

sales representatives failed to disclose that they worked for Shire. Shire sales representatives provided these prior authorization services to physicians to induce the physicians to prescribe Vyvanse paid for by the State's Medicaid Program. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Daytrana. From April 2006 to September 2010, Shire was aware that its Daytrana patches at times demonstrated difficulty in sticking to the patient's body and separating from the packaging. As a result, some patients either received less therapy than the patch was supposed to provide – *i.e.*, where the patch would fall off prematurely – or received no therapy from the patch because it could not be separated from the packaging. In addition, beginning in April 2006, certain Shire sales representatives marketed Daytrana as less abuseable than traditional, pill-based medications, despite a lack of clinical data sufficient to support such a claim.

Furthermore, from April 2006 through July 2008, certain Shire sales representatives knowingly and improperly made phone calls and drafted letters to Medicaid to assist physicians with the prior authorization process for Medicaid prescriptions of Daytrana. When contacting Medicaid in connection with the prior authorization process, certain Shire sales representatives failed to disclose that they worked for Shire. Shire sales representatives provided these prior authorization services to physicians to induce the physicians to prescribe Daytrana paid for by the State's Medicaid Program. The State further alleges that as a result of the behavior described

above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Lialda. From January 2007 through June 2010, certain Shire sales representatives promoted Lialda for the prevention of colorectal cancer, an indication for use which was not approved by the FDA; was not a medically accepted indication, as defined by 42 U.S.C. § 1396r-8(k)(6); and was not covered by the State's Medicaid Program. Certain sales representatives promoted Lialda by linking increased tissue concentration and a slower dissolution rate to increased efficacy, despite a lack of clinical data sufficient to support such claims. Shire also marketed Lialda based, in part, on claims that the medication had greater efficacy than other medications, specifically, that Lialda would induce "complete remission" of mild to moderate ulcerative colitis, despite a lack of clinical data sufficient to support such a claim. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Pentasa. From January 2006 through June 2010, certain Shire sales representatives promoted Pentasa for the treatment of indeterminate colitis, an indication for use which was not approved by FDA; was not a medically accepted indication, as defined by 42 U.S.C. § 1396r-8(k)(6); and was not covered by the State's Medicaid Program. Additionally, during the same time period, Shire promoted Pentasa for the treatment of Crohn's disease, an indication for use which was not approved by the FDA. The State further alleges that as a result of the behavior described above, Shire knowingly

caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Shire's conduct as described immediately above in Section II.G. as to the Covered Drugs will hereinafter be referred to as the "Covered Conduct."

H. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Shire nor a concession by the State that its claims are not well founded. Shire expressly denies the allegations of the State and the Relators set forth herein and in the Civil Actions.

I. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, 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. Shire shall pay to the United States and the Medicaid Participating States (as defined in subparagraph (c) below), collectively, the sum of Fifty-Six Million Five Hundred Thousand Dollars (\$56,500,000.00), plus interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment 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 be forever discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Shire shall pay to the United States the sum of \$35,713,965.22, plus accrued interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment as set forth above (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Shire shall pay to the Medicaid Participating States the sum of \$20,786,034.78, plus interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of subparagraph (c) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 57 day opt-in period for Medicaid Participating States as described in subparagraph (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 Shire.

(c) Shire shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Shire and the State Team have agreed, or in a form otherwise agreed to by Shire and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the

State and delivered to counsel for Shire within 57 days of receiving this Agreement. If this condition is not satisfied within 57 days, Shire's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Shire and the State Team to extend the 57 day period.

(d) The total portion of the amount paid by Shire in settlement for the Covered Conduct to the State is \$2,788,361.83, consisting of an amount 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 \$967,290.68, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 57 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Shire absent written agreement between counsel for Shire 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 Shire in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Actions. Contingent upon the receipt of their respective State Amounts, the State, if served with the Civil Actions and liable to pay a Relator's share, agrees to pay the Relators the amount of \$181,836.03, plus applicable interest, agreement as to which shall be set forth in side letters issued to and executed by the Relators in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Shire 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 Shire, together with its current and former parent corporations; current and former direct and indirect subsidiaries; current and former brother or sister corporations; current and former divisions; current and former owners; current and former affiliates; current and former directors, officers, and employees; and the predecessors, successors, transferees, and assigns of any of them (the "Shire Released Parties") from any civil or administrative monetary claim that the State has 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 of the Shire Released Parties, 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; and (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 based upon obligations created by this Agreement;
- (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(g) except with respect to Daytrana, any liability for express or implied warranty claims or other claims for defective or deficient products and services provided by Shire;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

(i) except with respect to Daytrana, any liability based on a failure to deliver goods or services due.

5. In consideration of the obligations of Shire set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") entered into between the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") and Shire North American Group, Inc. 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 Shire plc, and Shire North American Group, Inc., and its operating subsidiaries for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against Shire in the event that Shire is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Shire 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

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, Shire 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 Shire has 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 Shire must pay to the State pursuant to Paragraph 1(d), 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 for the Covered Conduct. Shire further agrees not to resubmit to the State's Medicaid Program 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. Shire shall not seek payment for any claims for reimbursement to the State Medicaid Program covered by this Agreement and attributable in any way to the Covered Conduct, from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

10. Shire 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)(1)(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 previously 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. The Parties do not release any claims 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 the purposes of the State's revenue code.

15. In addition to all other payments and responsibilities under this Agreement, Shire agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Shire 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. Upon receipt of the payments described in Paragraph 1(d), above, the State, in connection with the Civil Actions, shall promptly sign and file a Stipulation of Dismissal of those Civil Actions pursuant to Rule 41(a)(1) as follows:

(a) the Stipulations of Dismissal shall be with prejudice to the State claims against Shire as to the Covered Conduct; and

(b) the Stipulations of Dismissal shall be without prejudice to the State as to all other claims.

17. 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.

18. The undersigned Shire 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.

19. 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.

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

21. 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.

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

STATE OF NORTH CAROLINA

By: Charles H. Hobergood

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

Dated: 7/23/2014

By: Robin G. Cummings

ROBIN G. CUMMINGS, M.D., Director
Division of Medical Assistance

Dated: 7/17/14

SHIRE

DATED: 9/17/14 BY: Ellen Rosenberg
Ellen Rosenberg
Senior Vice President and Associate General Counsel

DATED: 9/17/14 BY: Melissa Bayer Tearney
R.J. Cinquegrana
Melissa Bayer Tearney
Counsel for Shire