

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and AstraZeneca LP and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca"), hereinafter collectively referred to as "the Parties."

II. PREAMBLE

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

A. AstraZeneca LP and AstraZeneca Pharmaceuticals LP are Delaware limited partnerships with their principal places of business in Wilmington, Delaware. At all relevant times, AstraZeneca distributed and sold pharmaceutical products in the United States.

B. On October 28, 2008, Ronald Streck ("Relator") filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States of America et al., ex. rel. Streck, et al. v. Allergan, et al.*, Civil Action No. 08-CV-5135, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S. § 3730(b) and the false claims statutes of the plaintiff states. Relator filed amended complaints on or about January 12, 2009, May 20, 2010, April 25, 2011, and September 29, 2011. AstraZeneca was named as a defendant in Relator's original and amended complaints. This *qui tam* action will be referred to as the "Civil Action."

C. AstraZeneca LP and AstraZeneca Pharmaceuticals LP have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement). "

D. The State contends that AstraZeneca caused claims for payment to be submitted to the Medicaid Program (see Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5). At all relevant times, AstraZeneca participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the Medicaid Program.

E. The State contends that it has certain civil and administrative claims or causes of action against AstraZeneca for engaging in the following conduct during the period from October 1, 2007 through June 30, 2014 (the "Covered Conduct"):

1. Pursuant to the Medicaid Drug Rebate Program, AstraZeneca was required to report the Average Manufacturer Price ("AMP") for each of its covered outpatient drugs to the Centers for Medicare and Medicaid Services ("CMS") on a monthly and quarterly basis, and to pay quarterly rebates to state Medicaid programs that were based, in part, on the quarterly AMPs reported by AstraZeneca. Prior to enactment of the Affordable Care Act ("ACA"), the AMP for a drug generally was based on the average unit price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade, including cash discounts and other price concessions that reduced the actual price paid for the drug. The ACA revised the definition of AMP, in part, by replacing the term "retail pharmacy class of trade" with "retail community pharmacies" and including manufacturer direct sales to pharmacies. Both before and

after enactment of the ACA, bona fide service fees are excluded from manufacturers' AMP calculations.

2. AstraZeneca entered into distribution services agreements with wholesalers ("Distribution Services Agreements") to facilitate the distribution and sale of the pharmaceuticals listed on Attachment A hereto ("the Covered Drugs"). Pursuant to the Distribution Services Agreements, the wholesalers performed various specified services, and AstraZeneca compensated the wholesalers for performing those services by providing the wholesalers quarterly credits calculated as a percentage of the quarterly sales of the Covered Drugs, subject to certain performance penalties based on criteria set forth in the agreements.

3. The State contends that AstraZeneca improperly treated compensation provided to the wholesalers pursuant to the Distribution Services Agreements as price reductions, rather than as bona fide service fees, in calculating and reporting quarterly AMPs to CMS for the Covered Drugs. As a result of AstraZeneca's reporting such improperly reduced AMPs, the State contends that AstraZeneca underpaid quarterly rebates owed to the states for the Covered Drugs under the Medicaid Drug Rebate Program, and caused the State Medicaid Program to be overcharged for the pharmaceuticals listed in the Distribution Services Agreements.

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by AstraZeneca, nor a concession by the State that its allegations are not well founded. AstraZeneca expressly denies the allegations of the State as set forth herein and Relator's allegations in the Civil Action.

G. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of the above claims and 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. AstraZeneca agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of \$46,500,000.00 plus accrued interest on that amount at a rate of 1.625% per annum commencing on February 20, 2015 and continuing until and including the day payment is made under this Agreement 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. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) AstraZeneca shall pay to the United States the sum of \$26,670,744.67, plus accrued interest on that amount at the rate of 1.625% per annum commencing on February 20, 2015 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) AstraZeneca shall pay to the Medicaid Participating States the sum of \$19,829,255.33, plus accrued interest ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 60 day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for AstraZeneca.

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

(d) The total portion of the amount paid by AstraZeneca in settlement for the Covered Conduct for the State is \$1,937,724.74, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The individual portion of the Medicaid State Settlement Amount

allocated to the State under this Agreement is the sum of \$601,865.38, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Settlement Agreement, the State Amount (including applicable interest), shall be deducted from the Medicaid State Settlement Amount and shall not be paid by AstraZeneca absent written agreement between counsel for AstraZeneca 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, including claims for restitution, damages, or civil fines or civil penalties, under state statutes currently pending against AstraZeneca in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon the receipt of its respective State Amount, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the Plaintiff-Relator through the State Team an amount to be determined by court hearing or by agreement between the State Team and the Plaintiff-Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of AstraZeneca 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 AstraZeneca, together with its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs and assigns, and all of their current and former directors, officers, agents, and employees, individually and collectively (collectively, the "AstraZeneca Released Parties"), from any civil or administrative monetary claims or causes of action that the State may have for any claims submitted or

caused to be submitted to the State Medicaid Program as a result of the Covered Conduct, or for the underpayment of Medicaid rebates to the State Medicaid Program as a result of the Covered Conduct. The payment of the Medicaid State Settlement Amount fully discharges the AstraZeneca Released Entities from any obligation to pay restitution, damages, civil fines, and/or civil penalties, to the State for 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 (other than State Medicaid Program liability for the Covered Conduct released in Paragraph 3 above);
- (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 AstraZeneca;

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

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

5. In consideration of the obligations of AstraZeneca set forth in this Agreement and a certification from AstraZeneca relating to government pricing practices in the United States, and conditioned upon AstraZeneca's full payment of the Medicaid Participating State 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 the AstraZeneca Released Parties for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against AstraZeneca in the event that AstraZeneca is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. AstraZeneca waive(s) 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, AstraZeneca waives and discharges the State, its agencies, employees, and agents from any causes of action (including claims for attorneys' fees, costs, and expenses of every kind and however denominated) which AstraZeneca has against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that AstraZeneca must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any 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, AstraZeneca 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 to withdraw the appeal of or not to appeal or cause the appeal of any such denials of claims.

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

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

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

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

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

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

(b) the Stipulation 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, 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 AstraZeneca 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 shall constitute an original, and all of which shall constitute one and the same Agreement.

STATE OF NORTH CAROLINA

By: Charles H. Hobbgood

Dated: 9/21/2015

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

By: Dave Richard

Dated: 9/10/15

DAVE RICHARD
Deputy Secretary for Medical Assistance
Division of Medical Assistance

ASTRAZENECA LP and ASTRAZENECA PHARMACEUTICALS LP

DATED: _____

BY: _____


PAUL HUDSON

President, US and Executive Vice
President, North America
Astra Zeneca LP and AstraZeneca
Pharmaceuticals LP

DATED: _____

BY: _____

ANDREW D. SCHAU
MATTHEW J. O'CONNOR
Covington & Burling LLP

and

DATED: _____

BY: _____

MICHAEL P. KELLY
McCarter & English LLP

Counsel for AstraZeneca LP and AstraZeneca
Pharmaceuticals LP

ASTRAZENECA LP and ASTRAZENECA PHARMACEUTICALS LP

DATED: _____

BY: _____

PAUL HUDSON
President, US and Executive Vice
President, North America
Astra Zeneca LP and AstraZeneca
Pharmaceuticals LP

DATED: 10/22/2015

BY: _____

ANDREW D. SCHAU
MATTHEW J. O'CONNOR
Covington & Burling LLP

and

DATED: 10/20/2015

BY: _____

MICHAEL P. KELLY
McCarter & English LLP

Counsel for AstraZeneca LP and AstraZeneca
Pharmaceuticals LP

**ATTACHMENT A
COVERED DRUGS**

NDC	DRUG NAME
00188000131	Lexxel 5-5mg 30x1TAB Bottle
00188000168	Lexxel 5-5mg 100x1TAB Bottle
00188000231	Lexxel 5-2.5 mg 30x1TAB Bottle
00185000431	Atacand 4mg
00188000831	Atacand 8mg
00188001828	Atacand 16m
00188001631	Atacand 16m
00188001654	Atacand 16m
00188003228	Atacand 32m
00188003231	Atacand 32m
00188003254	Atacand 32m
00188018228	Atacand HCT
00188018254	Atacand HCT
00188021203	Xylocaine Inj 1.5% Spinal w/Dextrose 10x2ML Package
00188026092	Xylocaine Inj 1.0% Epi:200 5x30ML Ampule Dispenser
00188032228	Atacand HCT
00188032254	Atacand HCT
00188032454	Atacand HCT
00188036011	Xylocaine Viscous 2% 1x450ML Package
00188037020	Symbicort 1
00188037028	Symbicort 1
00188037220	Symbicort 8
00188037228	Symbicort 8
00188042504	Budesonide
00188042604	Budesonide
00188045028	Plendil 2.5mg 100x1TAB Hospital Unit Dose
00188045058	Plendil 2.5mg 100x1TAB Bottle
00188045128	Plendil 5mg 100x1TAB Hospital Unit Dose
00188045158	Plendil 5mg 100x1TAB Bottle
00188045228	Plendil 10mg 100x1TAB Hospital Unit Dose
00188045258	Plendil 10mg 100x1TAB Bottle
00188051080	Vimovo 375
00188052039	Vimovo 500
00188052080	Vimovo 500
00188060831	Prilosec 10
00188060882	Prilosec 10
00188061001	Prilosec Fo
00188062501	Prilosec Fo

00186070210	Entocort EC
00186074231	Prilosec 20
00186074282	Prilosec 20
00186074331	Prilosec 40
00186074368	Prilosec 40
00186074382	Prilosec 40
00186077739	Brilinta 90
00186077760	Brilinta 90
00186091542	Pulmicort Turbuhaler 200mcg 1x1EA Turbuhaler
00186091612	Pulmicort F
00186091706	Pulmicort F
00186107008	Rhinocort A
00186108805	Toprol-XL 2
00186108839	Toprol-XL 2
00186109005	Toprol-XL 5
00186109039	Toprol-XL 5
00186109050	Toprol-XL 50mg 30 count dose package
00186109205	Toprol-XL 1
00186109239	Toprol-XL 1
00186109405	Toprol-XL 2
00186190501	Foscavir 24mg/mL 250mL IV 12x250ML Package
00186190601	Foscavir 24mg/mL 500mL IV 12x500ML Package
00186198804	PULMICORT R
00186198904	PULMICORT R
00186199004	PULMICORT R
00186401001	Nexlum For
00186402001	Nexlum For
00186402501	Nexlum For
00186404001	Nexlum For
00186406001	Nexlum For
00186423921	Aquasol A 50,000 USP Units/2mL 10x2ML Package
00186502031	Nexlum 20mg
00186502054	Nexlum 20mg
00186502082	Nexlum 20mg
00186502228	Nexlum 20mg
00186504031	Nexlum 40mg
00186504036	Nexlum 40mg
00186504054	Nexlum 40mg
00186504055	Nexlum 40mg
00186504082	Nexlum 40mg
00186504085	Nexlum 40mg
00186504225	Nexlum 40mg
00186504228	Nexlum 40mg
00186802001	Nexlum IV f

00186604001	Nexlum IV f
00186730005	Metoprolol Succinate 25mg 100x1 TAB BTL
00186730105	Metoprolol Succinate 50mg 100x1 TAB BTL
00186730205	Metoprolol Succinate 100mg 100x1 TAB BTL
00186730305	Metoprolol Succinate 200mg 100x1 TAB BTL
00310010110	Tenormin 10
00310010510	Tenormin 50
00310010710	Tenormin 25
00310010810	Tenormin I.V. Inj 6x10mL 5 mg/10 mL AMP
00310011510	Tenoretic 5
00310011710	Tenoretic 1
00310013010	Zestril 5mg 1x100TAB Bottle
00310013011	Zestril 5 m
00310013039	Zestril 5mg 1x100TAB Hospital Unit Dose
00310013110	Zestril 10m
00310013111	Zestril 10m
00310013210	Zestril 20m
00310013211	Zestril 20m
00310013310	Zestril 30mg 1x100TAB Bottle
00310013311	Zestril 30m
00310013410	Zestril 40m
00310013510	Zestril 2.5
00310014110	Zestoretic 10/12.5mg 1x100TAB Bottle
00310013411	Zestril 40
00310013510	Zestril 2.5
00310013511	Zestril 2.5
00310014111	Zestoretic
00310014210	Zestoretic
00310014211	Zestoretic
00310014510	Zestoretic
00310014511	Zestoretic
00310020130	Arimidex 1m
00310020150	Arimidex 1mg 30 count dose package
00310020860	Zomig Nasal
00310020920	Zomig-ZMT 2
00310021020	Zomig 2.5mg
00310021125	Zomig 5mg 1
00310021321	Zomig-ZMT 5
00310027110	Seroquel 10
00310027139	Seroquel 10
00310027210	Seroquel 20
00310027239	Seroquel 20
00310027439	Seroquel 30
00310027460	Seroquel 30

00310027510	Seroquel 25
00310027534	Seroquel 25
00310027539	Seroquel 25
00310027810	Seroquel 50
00310027834	Seroquel 50
00310027839	Seroquel 50
00310027910	Seroquel 40
00310027939	Seroquel 40
00310028039	Seroquel XR
00310028060	Seroquel XR
00310028139	Seroquel XR
00310028160	Seroquel XR
00310028239	Seroquel XR
00310028255	Seroquel XR 200mg 1x500 Tablet Bottle
00310028260	Seroquel XR
00310028339	Seroquel XR
00310028355	Seroquel XR 300mg 1x500 Tablet Bottle
00310028360	Seroquel XR
00310028439	Seroquel XR
00310028455	Seroquel XR 400mg 1x500 Tablet Bottle
00310028460	Seroquel XR
00310032130	Merrem I.V.
00310032165	NOVAPLUS Me
00310032520	Merrem I.V.
00310032584	NOVAPLUS Me
00310037610	Cefotan Inj 1g/10mL 10x1EA VIAL
00310037720	Cefotan Inj 2g/20mL 10x1EA VIAL
00310037851	Cefotan Inj 1g/50mL 1x1EA (Galaxy Bag)
00310037951	Cefotan Inj 2g/50mL 1x1EA (Galaxy Bag)
00310040160	ACCOLATE 10
00310040239	ACCOLATE 20mg
00310040280	ACCOLATE 20
00310048230	Iressa 250m
00310060060	Nolvadex 10mg 1x60TAB Bottle
00310060430	Nolvadex 20mg 1x30TAB Bottle
00310070610	Casodex 50m
00310070630	Casodex 50m
00310070639	Casodex 50m
00310072010	Faslodex 50
00310072025	Faslodex 250mg/5ml 2 X 2 5 ML Pre-filled Syringe
00310072050	Faslodex 25
00310075139	Crestor 10m
00310075190	Crestor 10m
00310075239	Crestor 20m

00310076290	Crestor 20m
00310076430	Crestor 40m
00310075590	Crestor 5mg
00310095038	Zoladex Saf
00310095130	Zoladex Saf
00310108730	Dutoprol 25
00310108530	Dutoprol 50
00310109730	Dutoprol 10
00310782030	Caprelsa 10
00310783030	Vandetanib
00310784030	Caprelsa 30