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ATTORNEY GENERAL

STATE OF NORTH CAROLINA

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March 31, 2017

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

Senator Warren Daniel
Senator Shirley Randleman
Senator Norman W. Sanderson
Representative James Boles, Jr.
Representative Ted Davis, Jr.
Representative Allen McNeill
Representative Rena W. Turner
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 Forest Laboratories, LLC/Forest Pharmaceuticals, Inc.

Dear Members:

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

A Settlement has been executed between Forest Labs/Forest Pharmaceuticals and the State of North Carolina.

The settlement resolves allegations that from January 1, 2008 through December 31, 2011, Forest Labs/Forest Pharmaceuticals paid kickbacks to certain physicians in order to induce those physicians to prescribe Bystolic, Savella, and Namenda.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$273,586.62. Of that amount the federal government will receive \$167,828.97 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 \$23,086.15 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$37,964.54 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 \$37,143.94 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 \$3,781.51 for investigative costs and \$3,781.51 for costs of collection.

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

Very truly yours,

AL / ...

Seth Dearmin Chief of Staff

SD:ng

cc: Kristine Leggett, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

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

II. PREAMBLE

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

- A. Forest Laboratories, LLC, is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is the parent of subsidiary Forest Pharmaceuticals, Inc., which engages in limited manufacturing of prescription pharmaceutical products in the United States. These entities will be referred to collectively hereafter as "Forest." Forest was acquired by Actavis plc on July 1, 2014. At all relevant times, Forest distributed, marketed, and sold pharmaceutical products in the United States, including the drugs sold under the trade names Bystolic®, Savella®, and Namenda® (the "Subject Drugs").
- B. On April 18, 2012, Kurt Kroening ("the Relator") filed a *qui tam* action in the United States District Court for the Eastern District of Wisconsin captioned *United States of America ex. rel Kurt Kroening, et al. v. Forest Pharmaceuticals, Inc., et al.*, Civil Action No. 12-CV-00366 (the "Civil Action"), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and several state False Claims Act and related statutes (the "State FCAs"). On January 31, 2014, the government plaintiffs filed a notice with the Court that they could not make an intervention decision at that time. On February 4, 2014, the Court ordered that the seal be lifted. The Relator filed his First Amended Complaint on June 13, 2014, alleging violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. On January 6, 2016, the Court entered an Order dismissing the First Amended Complaint. On February 5, 2016, Relator filed his Second Amended Complaint, which alleged, among other things, that Forest paid illegal remuneration, in

²¹ Following its acquisition of Allergan, Inc. in March 2015, Actavis plc changed its name to Allergan plc. Forest Laboratories, Inc., Forest Pharmaceuticals, Inc. Case # 15-02-01

violation of the Anti-Kickback Statute, to physicians who purportedly gave presentations on behalf of Forest. The United States and the following States are named plaintiffs in the Second Amended Complaint: Arkansas; California; Colorado; Connecticut; Delaware; Florida; Georgia; Hawaii; Illinois; Indiana; Iowa; Louisiana; Massachusetts; Michigan; Minnesota; Montana; Nevada; New Jersey; New Mexico; New York; North Carolina; Oklahoma; Rhode Island; Tennessee; Texas; Virginia; Wisconsin; and the District of Columbia. This *qui tam* action will be referred to collectively as the "Civil Action."

- C. Forest has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement) hereinafter referred to as the "United States."
- D. The State contends that Forest caused claims for payment for the Subject Drugs to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396w-5) in violation of the Anti-Kickback Statute ("AKS") and state anti-kickback statutes.
- E. The State contends that it has certain civil and administrative causes of action against Forest arising from Forest having paid kickbacks to physicians in order to induce them to prescribe the Subject Drugs. Specifically, the State contends that, between January 1, 2008 and December 31, 2011, Forest knowingly caused false and/or fraudulent claims to be submitted to the state Medicaid Program for the Subject Drugs by paying kickbacks, which took the form of honoraria payments and meals, to certain physicians who were to make one or more presentations to other health care professionals about Bystolic® or Savella®, or nine or more presentations to other health care professionals about Namenda®, during that time period, in order to induce those physicians to prescribe the "Subject Drugs." Examples of such inducements include, but are not limited to, payments made in instances in which (1) the physician did not make a presentation either because the program was cancelled (and there is no record of a bona fide reason for the cancellation) or because no attendees appeared; (2) the physician made a presentation when there were no licensed health care professionals in attendance; (3) the physician made a presentation to attendees, including in some cases the physician's colleagues or staff members who, over a short period of time, attended multiple

presentations about the same drug; or (4) the meals associated with the presentations at times exceeded Forest's own internal cost limitations. The State alleges that this conduct resulted in Forest knowingly submitting or causing the submission of false and/or fraudulent claims to the State Medicaid Program, and is referred to as the "Covered Conduct."

- F. This Agreement is neither an admission of facts or liability by Forest nor a concession by the State that its allegations are not well founded. Forest expressly denies the allegations of the State as set forth herein and in the Civil Action.
- G. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

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

- 1. Pursuant to the separate Federal Settlement Agreement, Forest shall pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of Thirty-Eight Million Dollars (\$38,000,000.00), plus accrued interest on that amount at the rate of 1.75% per annum commencing on June 15, 2016 and continuing and including the day payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:
- (a) Forest shall pay to the United States the sum of Thirty-Five million, Four Hundred Fifty-Three Thousand, Seven Hundred Fourteen Dollars and Ninety-Six Cents (\$35,453,714.96), plus accrued interest on that amount at the rate of 1.75% per annum commencing on June 15, 2016, and continuing until and including the date of payment as

set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

- (b) Forest shall pay to the Medicaid Participating States, collectively, the sum of Two Million, Five Hundred Forty-Six Thousand, Two Hundred Eighty-Five Dollars and Four Cents (\$2,546,285.04), plus accrued interest at the rate of 1.75% per annum commencing on June 15, 2016 ("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 ten (10) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid 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 Forest.
- (c) Forest shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Forest and the State Team have agreed, or in a form otherwise agreed to by Forest and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Forest's attorneys within 60 days of receiving this Agreement. If this condition is not satisfied within 60 days, Forest's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Forest and the State Team to extend the 60-day period.
- (d) The total portion of the amount paid by Forest in settlement for the Covered Conduct for the State is \$272,766.02, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$104,937.05, 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 shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Forest absent written agreement between counsel for Forest 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 Forest in State or Federal Courts for the Covered Conduct, with prejudice, and without prejudice as to any other pending claims, 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 Relator the amount of \$23,086.15, plus applicable interest. This amount is to be paid through the State Team and has been addressed via a side letter with the Relator in the Civil Action.
- 3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Forest 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 Forest, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns, (collectively, the "Forest Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct. The payment of the Medicaid State Settlement Amount fully discharges the Forest Released Entities from any obligations to pay Medicaid restitution, Medicaid damages, and/or any Medicaid civil fine or civil penalty 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;

- (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 express or implied warranty claims or other claims for defective or deficient products and services provided by Forest;
- (i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
 - (i) any liability based on a failure to deliver goods or services due: or
 - (k) any liability of individuals.
- 5. The State expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Forest and/or its officers, directors, and employees from the State's Medicaid program (as defined in 42 U.S.C. 1320a-7b(f) under 1320a-7(a) (mandatory exclusion) or 42 U.S.C.1320a-7(b) or 42 U.S.C. 1320a-7a (permissive exclusion) for the Covered Conduct.
- 6. Forest 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 that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution, or under the Excessive Fines Clause of the Eighth Amendment of the Constitution, 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, Forest waives and discharges the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Forest has against the State, its agencies, employees, and agents arising from the State's civil investigation and prosecution of the Covered Conduct.

- 8. The amount that Forest 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 Forest 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. Forest shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.
- 10. Forest 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 only, and by this instrument the Parties do not release any liability against any other person or entity.
- 14. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.
- 15. In addition to all other payments and responsibilities under this Agreement, Forest agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses for work relating to this Agreement. Forest will pay this amount by separate check made payable to the National

Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

- 16. This Agreement is governed by the laws of the State, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.
- 17. The undersigned Forest signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.
- 18. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.
- 19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.
- 20. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.
- 21. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

STATE OF NORTH CAROLINA

By:	Colore H. HOUJOOA	Dated: 1/18/2017
		
	CHARLES H. HOBGOOD	
	Director, Medicaid Investigations Division	
	Office of the Attorney General	

DAVE RICHARD

Deputy Secretary for Medical Assistance Division of Medical Assistance

FOREST LABORATORIES, LLC & FOREST PHARMACEUTICALS, INC. – DEFENDANTS

DATED: 2/15/17	BY:	
	A. ROBERT D. BAILEY	
	Vice President	
•	Forest Laboratories, LLC	
	Morris Corporate Center III	
	400 Interpace Parkway	
	Parsippany, NJ 07051	

DATED: _____ BY: ____

MARK P. GOODMAN
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919 Third Avenue
New York, NY 10022
Counsel for Forest Laboratories, LLC and
Forest Pharmaceuticals, Inc.

FOREST LABORATORIES, LLC & FOREST PHARMACEUTICALS, INC. – DEFENDANTS

DATED:	BY:	•
		A. ROBERT D. BAILEY
		Vice President
•		Forest Laboratories, LLC
		Morris Corporate Center III
	•	400 Interpace Parkway
		Parsippany, NJ 07051
DATED: 2/15/17	BY:	MARK P. GOODMAN KRISTIN D. KIEHN Debevoise & Plimpton LLP 919 Third Avenue New York, NY 10022 Counsel for Forest Laboratories, LLC and Forest Pharmacouticals, Inc.