



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

February 7, 2019

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 Danny Earl Britt, Jr.
Senator Warren Daniel
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 Abbott Laboratories

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 Abbott and the State of North Carolina.

The settlement resolves allegations that from January 1, 2006 through December 31, 2008, Abbott off-label marketed TriCor for uses not approved by the FDA and paid kickbacks to physicians to induce them to prescribe TriCor.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$168,559.68. Of that amount the federal government will receive \$109,330.28 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$29,064.35 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 \$26,445.93 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. § 1-608(c), the North Carolina Department of Justice will receive \$5,013.77 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,



Seth Dearmin
Chief of Staff

SD:ng

cc: John Poteat, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State"), Abbott Laboratories and AbbVie Inc. (collectively "the Abbott Parties"), hereafter referred to as "the Parties."

II. PREAMBLE

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

A. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. At all relevant times, Abbott marketed the drug fenofibrate under the trade name of TriCor® as part of its research-based pharmaceuticals business. As of January 1, 2013, Abbott completed the separation of its research-based pharmaceuticals business, which became an independent company, AbbVie Inc. AbbVie Inc. is a Delaware corporation with its principal place of business in North Chicago, Illinois.

B. On September 18, 2009, Relator filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States ex rel. Amy Bergman, et al. v. Abbott Laboratories, Civil Action No. 09-04264, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. §3730(b). The operative amended complaint was filed on January 6, 2012, and is captioned United States ex rel. Amy Bergman, et al. v. Abbott Laboratories, Civil Action No. 2:09-cv-04264 ("Civil Action"). The United States declined to intervene in the Civil Action on March 22, 2012 and the States declined August 14, 2012.

C. The Abbott Parties have entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States of America” (“United States”) as that term is defined in the Federal Settlement Agreement.

D. The State contends that the Abbott Parties caused claims for payment to be submitted to the State’s Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

E. The State contends that it has certain civil and administrative causes of action against the Abbott Parties for engaging in the following conduct (the “Covered Conduct”): During the period from January 1, 2006 through December 31, 2008, Abbott:

1. Marketed and sold TriCor® (1) for use in treating, preventing or reducing cardiovascular events and other cardiac health risks, (2) for use in combination with statin drugs, and (3) for first-line treatment of diabetic patients, including treatment to prevent or reduce cardiac health risks in diabetic patients—uses that were not FDA-approved and were not covered by Medicaid; and
2. Provided or offered to provide remuneration to physicians including, but not limited to, in-office meals and snacks, gifts, gift baskets and certificates, and engaged health care providers for speaking engagements and consulting services where at least one purpose of the remuneration was to induce the physicians to prescribe TriCor®.

The State further contends that Abbott knowingly caused false or fraudulent claims to be submitted for reimbursement to the Medicaid program during the time period specified above.

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

G. 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. The Abbott Parties agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of \$25,000,000.00, of which \$12,500,000.00 and a pro-rata share of accrued interest is restitution (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, as defined therein 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) The Abbott Parties shall pay to the United States the sum of \$23,166,388 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total portion of the amount paid by the Abbott Parties for the Covered Conduct for the States (subject to the non-participating state deduction provision of sub-paragraph (d) below) is \$4,024,609 consisting of a portion paid to the States under this

Agreement of \$1,833,612 and another portion paid to the United States as part of the Federal Settlement Agreement of \$2,190,997. The Abbott Parties shall pay to the Medicaid Participating States the sum of \$1,833,612 plus a pro rate share of the accrued interest (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below (the "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 and the date of receipt of any necessary payment information. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited 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 (the "State Team"), which written instructions shall be delivered to counsel for the Abbott Parties. The electronic funds transfer shall constitute tender and negotiation of the Medicaid State Settlement Amount as defined in Paragraph III. 1. (d) below.

(c) The Abbott Parties shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which the Abbott Parties and the State Team have agreed, or in a form otherwise agreed to by the Abbott Parties and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to the Abbott Parties' attorneys within 60 days of receiving this Agreement. The Abbott Parties' offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Abbott and the State Team to extend the 60-day period.

(d) The total amount paid by the Abbott Parties in settlement for the Covered Conduct for the State is \$168,559.68, 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 \$59,229.40 plus applicable interest (the "State Amount"), of which \$29,614.70 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by the Abbott Parties absent written agreement between counsel for the Abbott Parties and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the Abbott Parties in State or Federal Courts for the Covered Conduct.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of the Abbott Parties set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release the Abbott Parties, together with their current and former parent corporations; direct and indirect subsidiaries; divisions; current or former corporate owners; and their corporate successors and assigns (collectively, the "the Abbott Parties Released Entities"), from any civil or administrative or 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 Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

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

(c) any civil or administrative liability that any person or entity, including the Abbott Parties 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; 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) any administrative liability for mandatory exclusions from the State's Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

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

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. The Abbott Parties waive 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 U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. 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, the Abbott Parties Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Abbott Parties Released Entities have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Abbott Parties 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 program payor, for the Covered Conduct; and the Abbott Parties agree not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and they agree to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

8. The Abbott Parties 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. The Abbott Parties expressly warrant that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

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

11. The Abbott Parties agree to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, the Abbott Parties shall facilitate, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available and facilitate the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals and of the Abbott Parties. Upon request, the Abbott Parties agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in their possession, custody or control, concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf, as well as complete and unredacted copies of any other non-privileged documents in their possession, custody, or control relating to the Covered Conduct. The Abbott Parties shall be responsible for all costs they may incur in complying with this paragraph.

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 the Parties do not release any liability as to 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, the Abbott Parties agree to pay the State Team's reasonable expenses and fees, including travel

costs, consultant expenses, and administrative fees. The Abbott Parties 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. Venue for addressing and resolving any and all disputes relating to this Agreement shall be in the state courts of appropriate jurisdiction of the State.

17. The undersigned Abbott Parties 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.

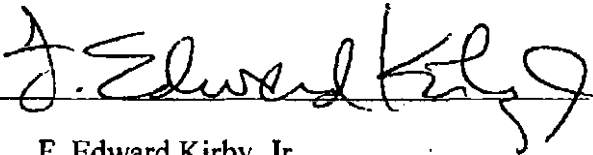
19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

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.

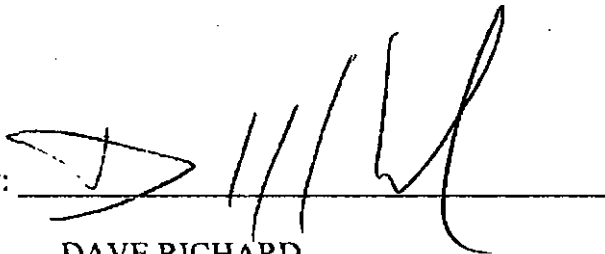
22. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By: 

F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

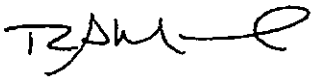
Dated: 11-27-18

By: 


DAVE RICHARD
Deputy Secretary, NC Medicaid
Division of Health Benefits

Dated: 11/15/2018

FOR ABBOTT PARTIES

By: 
Robert A. Michael
Senior Vice President, Chief Financial Officer
AbbVie, Inc.

Dated: 12-21-18

By: 
Henry J. DePippo
Counsel for Abbott Parties
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022

Dated: 12/21/2018