



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

December 2, 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
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 Reckitt Benckiser

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 Reckitt Benckiser and the State of North Carolina.

The settlement resolves allegations that from January 1, 2010 through December 31, 2014, Reckitt knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions (a) without any counseling or psychosocial support, such that the prescriptions were not for a medically accepted indication; and (b) for uses that were unsafe, ineffective, and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose. It was also alleged that Reckitt promoted the sale of Suboxone Film using false and misleading claims that it was less subject to diversion and abuse than other buprenorphine products.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$14,864,317.68. Of that amount the federal government will receive \$8,753,725.80 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 \$1,055,369.32 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$2,383,028.72 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 \$2,462,654.40 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 \$209,539.44 for investigative costs and costs of collection.

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

Sincerely,



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") and Reckitt Benckiser Group plc and Reckitt Benckiser LLC, formerly d/b/a Reckitt Benckiser Inc. (collectively, "RB Group") (hereafter, the State and RB Group are 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. Reckitt Benckiser Group plc is an English public limited company headquartered in Slough, England, the United Kingdom. Reckitt Benckiser LLC is a subsidiary of Reckitt Benckiser Group plc and is headquartered in New Jersey. At all relevant times through December 23, 2014, Reckitt Benckiser Pharmaceuticals, Inc. was a subsidiary of RB Group that distributed, marketed, and sold pharmaceutical products in the United States, including a drug sold under the trade names Suboxone Sublingual Tablet ("Suboxone Tablet") and Suboxone Sublingual Film ("Suboxone Film") (collectively, "Suboxone"). Suboxone Tablet and Film both contain a combination of buprenorphine (an opioid) and naloxone (an opioid antagonist) and were approved to suppress opioid withdrawal symptoms as part of a complete treatment plan to include counseling and psychosocial support. In 2014, Reckitt Benckiser Pharmaceuticals, Inc. was spun off as a separate corporation and renamed Indivior, Inc.

B. *Qui Tam* Actions:

(1) On January 25, 2010, Stefan Kruszewski filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States of America et Reckitt Benckiser #421*

al., ex rel. Stefan Kruszewski v. UNDER SEAL, Civil Action No. XX-cv-XXXX. Relator amended the complaint several times, culminating with a Fourth Amended Complaint filed on August 25, 2017.

(2) On October 12, 2012, Stuart Finkelstein, M.D. filed a *qui tam* action in the United States District Court for the Central District of California captioned *United States of America et al., ex rel. Stuart Finkelstein, M.D. v. Reckitt Benckiser Pharmaceuticals, Inc., et al.*, Civil Action No. 12-cv-8797. Relator amended the complaint on January 2, 2013, and filed a Second Amended Complaint on January 14, 2014. On August 27, 2014, the action was transferred to the Western District of Virginia as Civil Action No. 1:14-cv-0059.

(3) On May 3, 2013, Ann Marie Williams filed a *qui tam* action in the United States District Court for the Western District of Virginia captioned *United States of America et al., ex rel. Ann Marie Williams v. Reckitt Benckiser, Inc., et al.*, Civil Action No. 1:13-cv-00036. Relator amended the complaint on February 24, 2014, and filed her Second Amended Complaint on December 14, 2016.

(4) On June 5, 2013, Gail Groves Scott filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States of America et al., ex rel. Gail Groves Scott v. UNDER SEAL*, Civil Action No. XX-cv-XXXX. Relator amended the complaint on December 3, 2013 and filed a Second Amended Complaint on December 29, 2016.

(5) On December 24, 2014, Christina Lemons filed a *qui tam* action in the United States District Court for the District of Arizona captioned *United States of America et al., ex rel. Christina Lemons v. Reckitt Benckiser Group plc, et al.*, Civil Action No. 14-

cv-2595. After the action was transferred to the Western District of Virginia as Civil Action No. 1:15-cv-16, Relator amended the complaint on February 19, 2015, filed the Second Amended Complaint on March 13, 2015, and filed the Third Amended Complaint on November 8, 2017.

(6) On June 12, 2018, Mitchel Greene filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States of America et al., ex rel. Mitchel Greene v. UNDER SEAL*, Civil Action No. XX-cv-XXXX.

These *qui tam* actions will be referred to collectively as the “Civil Actions.”

C. RB Group has 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 RB Group directly or through its subsidiaries submitted or caused to be submitted claims for payment 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 RB Group for engaging in the following conduct between January 1, 2010, and December 31, 2014 (the “Covered Conduct”):

(a) The State contends that RB Group directly or through its subsidiaries knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions (a) without any counseling or psychosocial support, such that the prescriptions were not for a medically accepted indication; and (b) for uses that were unsafe, ineffective, and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose. Such prescriptions lacking a legitimate medical purpose are also not for a medically accepted indication.

(b) The State contends that RB Group directly or through its subsidiaries

knowingly promoted the sale or use of Suboxone Film using false and misleading claims that Suboxone Film was less subject to diversion and abuse than other buprenorphine products and that Suboxone Film was less susceptible to accidental pediatric exposure than Suboxone Tablets. Physicians relied on these false and misleading claims in prescribing Suboxone Film, and the State's Medicaid Program relied on these false and misleading claims to their detriment in making formulary and prior authorization decisions.

- (c) The State contends that RB Group directly or through its subsidiaries knowingly submitted a petition to the Food and Drug Administration on September 25, 2012, fraudulently claiming that Suboxone Tablet had been discontinued "due to safety concerns" about the tablet formulation of the drug and took other steps to fraudulently delay the entry of generic competition for Suboxone in order to improperly control pricing of Suboxone, including pricing to the State's Medicaid Program.

F. This Agreement is neither an admission of facts or liability by RB Group, nor a concession by the State that its allegations are not well founded. RB Group denies the allegations in the Covered Conduct and in the Civil Actions.

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. RB Group agrees 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 Seven Hundred Million Dollars (\$700,000,000) (the "Settlement Amount"), plus, as to the Medicaid Participating States, accrued interest, as set forth below. 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) On July 22, 2019, RB Group paid to the United States the sum of \$500,000,000 pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$467,071,461.93, consisting of \$200,000,000 for the states pursuant to this Agreement, which RB Group placed into an interest-bearing account on July 22, 2019, and \$267,071,461.93 for the United States. RB Group shall pay to the Medicaid Participating States the sum of \$200,000,000 plus any accrued interest on that amount from July 22, 2019 to and including the day payment is made under this Agreement (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (d) below (the “Medicaid Participating State Settlement Amount”). Such payment shall be made no later than seven (7) business days after the expiration of the 45-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. 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 RB Group. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III.1.(d) below.

(c) RB Group shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which RB Group and the State Team have agreed, or in a form otherwise agreed to by RB Group and an individual State. The State shall constitute a Medicaid

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Participating State provided this Agreement is fully executed by the State and delivered to RB Group attorneys within 45 days of receiving this Agreement. RB Group's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for RB Group and the State Team to extend the 45-day period.

(d) The total portion of the amount paid by RB Group in settlement for the Covered Conduct for the State is \$14,840,054.06, 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 \$6,086,328.26 plus applicable interest (the "State Amount"), of which \$3,043,164.13 is restitution. If the State does not execute this Agreement within 45 days of receiving this Agreement, the State Amount and any accrued interest on that amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by RB Group absent written agreement between counsel for RB Group and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount by the New York State Attorney General's National Global Settlement Account pursuant to Paragraph III.1.(b), the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against RB Group in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Actions. Contingent upon payment of the State Amount, the State, if served with any of the Civil Actions and otherwise liable to pay a relator's share, agrees to pay the relators, as soon as feasible after receipt of such payment, such amounts as have been or will be negotiated with the relators in the Civil Actions, 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 RB Group set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Reckitt Benckiser Group plc, and any and all current affiliated entities, including but not limited to Reckitt Benckiser LLC (formerly d/b/a Reckitt Benckiser Inc.), Reckitt Benckiser Healthcare (UK) LTD., Reckitt Benckiser (North America) Inc., and Reckitt Benckiser USA General Partnership (collectively, the "Defendant 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 Covered Conduct; any statutory provision creating a cause of action for civil damages or civil penalties which the State has actual or present authority to assert for the Covered Conduct, including the State's counterpart to the federal False Claims Act; or any common law theories, including payment by mistake, unjust enrichment, fraud, nuisance, or negligent entrustment for the Covered Conduct. This Paragraph III.3 does not release any claims the State may have against Indivior PLC, Indivior Inc. (f/k/a Reckitt Benckiser Pharmaceuticals, Inc.), or their predecessors, or their current subsidiaries, or any of their former subsidiaries not currently owned by Reckitt Benckiser Group plc (collectively, "Indivior").

4. Notwithstanding the releases given in Paragraph III.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 the State's revenue code;
- (b) any criminal liability;

(c) any civil or administrative liability that any person or entity, including the Defendant Released Entities, have 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 III.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) 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;

(j) any liability of individuals;

(k) any liability for the claims or conduct alleged in the operative complaints provided to counsel for RB Group, by counsel for the United States, in connection with the negotiation of the Federal Settlement Agreement in the following *qui tam* actions, and no setoff related to amounts paid under this Agreement shall be applied to any recovery in connection with either of these actions:

- *United States ex rel. Miller v. Reckitt Benckiser Group plc*, Case No.

1:15-cv-00017 (W.D. Va.); and

- *Sealed v. Sealed*, Case No. X:XX-cv-XXXX (S.D.N.Y.); and

(l) any liability of Indivior. However, the State shall not seek further recovery from RB Group arising out of a civil judgment against Indivior for the Covered Conduct. This provision shall not affect any rights or claims that may exist between Indivior and RB Group.

5. In consideration of the obligations of RB Group set forth in this Agreement, and conditioned on receipt of the State Amount by the New York State Attorney General's National Global Settlement Account pursuant to Paragraph III.1.(b), 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 RB Group for the Covered Conduct. Nothing in this Agreement precludes the State from taking action against RB Group in the event that RB Group is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. RB Group 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 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.

7. In consideration of the obligations of the State set forth in this Agreement, the Defendant 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 claims or causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Defendant 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 as of the date of this Agreement.

8. The amount that RB Group 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 RB Group agrees 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 agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

9. RB Group 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. RB Group expressly warrants 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.

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.

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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, RB Group agrees to pay the State Team's reasonable expenses and fees, including State Team telephonic costs, consultant expenses, and administrative fees. RB Group 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 RB Group 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.

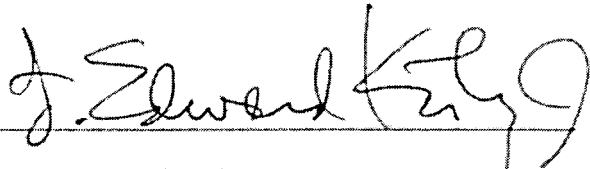
19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

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.

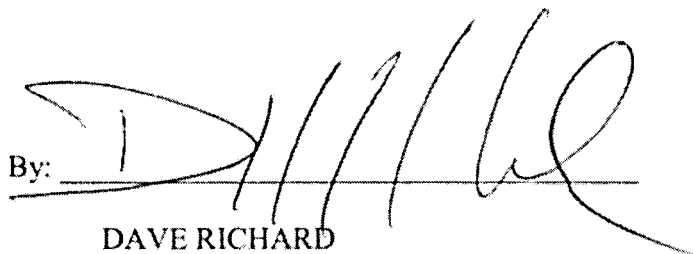
22. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By: 

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

Dated: 9-13-19

By: 

DAVE RICHARD
Deputy Secretary, NC Medicaid
Division of Health Benefits

Dated: 9/5/2019

RECKITT BENCKISER GROUP plc

By: Luc Bondy Dated: 10-16-19 CEB

MR R BONDY
Name

SVP GC & COMPANY SECRETARY
Title

RB
Organization

By: Howard M. S. Legier Dated: 10-16-19

Wilmer Cutler Pickering Hale and Dorr LLP
Counsel to RBG plc

RECKITT BENCKISER LLC

By: Russ Bondy Dated: 10-16-19

MR R BONDY
Name

SVP GIL & COMPANY SECRETARY
Title

RB
Organization

By: Howard M. S. Legio Dated: 10-16-19

Wilmer Cutler Pickering Hale and Dorr LLP
Counsel to RB LLC