



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

January 22, 2021

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 Royal
Pharmaceuticals, LLC

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.

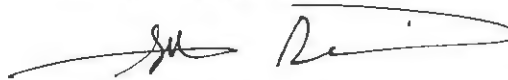
A settlement has been executed between Royal Pharmaceuticals, LLC and the State of North Carolina.

The settlement resolves allegations that from September 1, 2013 through January 31, 2017, Royal Pharmaceuticals failed to correctly report the proper "Market Date" for the Medicaid Drug Rebate Program. As a result, an incorrect "Market Date" data element was used by the Centers for Medicare and Medicaid Services in the "Baseline AMP" calculus within the Drug Data Reporting system that is used to calculate rebates to be paid to the State under the Medicaid Drug Rebate Program.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$684,219.89. Of that amount the federal government will receive \$383,473.95 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$282,029.72 as restitution and interest. Pursuant to G.S. § 1-608(c), the North Carolina Department of Justice will receive \$18,716.22 for investigative costs.

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

Very truly yours,

A handwritten signature in black ink, appearing to read 'Seth Dearmin', is written over a horizontal line.

Seth Dearmin
Chief of Staff

SD:ng

cc: William Childs, NCGA Fiscal Research Division
Mark White, NCGA Fiscal Research Division
Morgan Weiss, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT WITH ROYAL PHARMACEUTICALS, LLC

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (“the State”) and Royal Pharmaceuticals, LLC (“the Company” or “Royal”), collectively, “the Parties.”

II. PREAMBLE

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

A. At all relevant times, Royal, a New Jersey Limited Liability Company with its principal place of business in Manasquan, New Jersey, distributed, marketed and/or sold pharmaceutical products in the United States to include three brand name formulations of Fluocinolone Acetonide. Royal is a privately held limited liability company.

B. The State contends that the Company 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.

C. The State contends that it has certain civil and administrative causes of action against the Company for engaging in the following conduct (the “Covered Conduct”):

As a participant in the Medicaid Drug Rebate Program (“MDRP”), the Company failed to correctly report the proper “Market Date” for its products NDC 68791-0102-04, NDC 68791-0101-04, and NDC 68791-0103-20 (“Products”). Specifically, rather than correctly reporting “Market Date” as the date of the first day the original NDA holder marketed the Products, the Company incorrectly reported the dates when the Company began marketing its Products after acquiring the marketing rights for those Products from the original NDA holder. As a result, an incorrect “Market Date” data element was used by the Centers for Medicare and

Medicaid Services (“CMS”) in the “Baseline AMP” calculus within the Drug Data Reporting (DDR) system that is used to calculate rebates to be paid to the State under the MDRP for the Products. Accordingly, from September 2013 until January 2017, when the error was discovered by the Company and the Company thereafter self-reported to CMS, the use of the incorrect “Market Date” data element in the “Baseline AMP” rebate calculus ultimately caused the Company to underpay its MDRP rebates to the State for its Products.

D. This Agreement is neither an admission of facts or liability by the Company nor a concession by the State that its allegations are not well founded.

E. 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 Company agrees to pay to the Medicaid Participating States (as defined in sub-paragraph (b) and subject to the non-participating state deduction provision of sub-paragraph (c) below), the sum of \$732,160.24 plus accrued interest (the “Settlement Amount”). The Settlement Amount shall constitute a debt immediately due and owing to the Medicaid Participating States on the “effective date” of the Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the Medicaid Participating States under the following terms and conditions:

(a) The Company shall pay to the Medicaid Participating States the sum of \$732,160.24 plus accrued interest on that amount of 0.75% per annum commencing on 08/30/2020 and continuing to and to include 10/30/2020 (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (c) below

(the “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 subparagraph (b) 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 the Company. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (c) below.

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

(c) The total portion of the amount paid by the Company in settlement for the Covered Conduct for the State is \$683,407.43 (“State Amount”), all of which is restitution. Of the State Amount, the State has determined that \$382,986.58 constitutes the Federal Medical Assistance Percentage (“FMAP”) and \$300,420.85 constitutes the State Medical Assistance Percentage (“SMAP”). 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 Company absent written agreement between counsel for the Company and the State Team to extend the time period for executing this Agreement.

2 The Parties acknowledge that the United States is entitled to the FMAP portion of the State Settlement Amount. The State has determined the FMAP amount in this matter, the payment of which shall be handled separately by and between the State and the United States. It is expressly understood and agreed that the State shall be solely responsible for determining and refunding the FMAP to the federal government, and that the FMAP shall be paid by the State from the State Amount. Company is not a party to any such FMAP obligation, determination, or payment, and takes no position regarding any such obligation, determination, or payment.

3 Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of the Company set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release the Company, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the “Company’s 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.

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 Company’s 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) claims

involving unlawful or illegal conduct based on 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; or
- (j) any liability of individuals

5. In consideration of the obligations of the Company set forth in this Agreement, and conditioned on receipt by the State of the State 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 Company for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against the Company in the event the Company is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. The Company 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 Company's 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 Company's 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.

8. The amount that the Company 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 Company 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. The Company 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 its parents, sponsors, legally responsible individuals, or third-party payors.

10. The Company expressly warrants that it has reviewed its financial conditions and that it has sufficient assets to pay the Settlement Amount and it has no present or future intention of filing bankruptcy; rather, the Company intends to continue operations.

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 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 Company agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. The Company 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 signatories for the Company 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. The facsimile, email or other electronically delivered signatures of the parties shall be deemed to constitute acceptable binding signatures for purposes of this Agreement, and facsimile or electronic copies shall be deemed to constitute duplicate originals.

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:  Dated: 10/19/2020

Dave Richard
Name

Deputy Secretary, NC Medicaid
Title

Department of Health & Human Services, Division of Health Benefits
Organization

By:  Dated: 10/20/2020

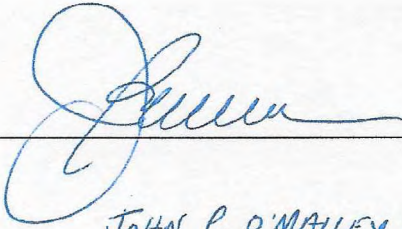
F. Edward Kirby, Jr.
Name

Director
Title

NCDOJ, Medicaid Investigations Division
Organization

ROYAL PHARMACEUTICALS, LLC

By:

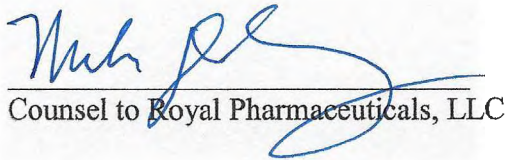


Dated: DECEMBER 11, 2020

JOHN P. O'MALLEY III
Name

CHIEF FINANCIAL OFFICER
Title

ROYAL PHARMACEUTICALS, LLC
Organization



Counsel to Royal Pharmaceuticals, LLC