



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

October 29, 2020

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 Pacira Pharmaceuticals

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Committee 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 Pacira Pharmaceuticals and the State of North Carolina.

The settlement resolves allegations that from December 1, 2012 through April 30, 2015, Pacira improperly issued research grants to physicians to generate prescriptions of its product Exparel.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$179,792.31. Of that amount the federal government will receive \$99,616.06 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 \$14,714.28 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$31,031.58 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 \$28,554.24 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 \$5,876.15 for investigative costs and costs of collection.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Seth Dearmin', followed by a large, stylized oval flourish.

Seth Dearmin
Chief of Staff

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 Pacira Pharmaceuticals, Inc. (“Pacira”), collectively, “the Parties.”

II. PREAMBLE

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

A. At all relevant times, Pacira, a New Jersey corporation with its principal place of business in Parsippany, New Jersey, distributed, marketed, and sold pharmaceutical products in the United States, including liposomal bupivacaine, a non-opioid analgesic, that was sold under the trade name EXPAREL.

B. On November 14, 2014, *Jordan C. Schneider* (the “Relator”) 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. Jordan C. Schneider v. Pacira Pharmaceuticals, Inc.*, Civil Action No. 2:14-cv-07021. This *qui tam* action will be referred to as the “Civil Action.”

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

D. The State contends that Pacira 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 Pacira for engaging in certain of the following conduct in the State (the “Covered Conduct”):

Pacira offered and/or paid illegal remuneration to health care providers, which remuneration Pacira intended, in whole or in part, to induce purchases of EXPAREL in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and analogous state statutes, as described more specifically in this paragraph. Specifically, the State contends that, during the period from December 1, 2012, through April 30, 2015, Pacira paid kickbacks in the form of 28 grants (collectively, the “Grants,” and each individually, a “Grant”) to certain health care providers and/or institutions, through which Pacira intended to spur sales of EXPAREL. Pacira has provided a list of the Grants that are the subject of the State’s contentions, which list also includes the names of the customers associated with each Grant and relevant volume of EXPAREL sales. The State contends that Pacira sales representatives or marketing executives typically initiated the Grants, which were conditioned upon acceptance of EXPAREL onto the institution’s formulary. The State contends that certain Pacira executives coached Grant recipients and other employees on how to avoid internal scrutiny of the Grant payments. The State contends that Pacira approved and funded the Grants despite receiving little or no documented description of the proposed research, and Pacira also did not document a reasonable commercial need or fair market value assessment for the Grants. The State contends further that after awarding the Grants, Pacira personnel conducted little or no follow-up on the proposed research, which certain Grant recipients did not carry out according to the original proposal, and sometimes did not perform at all. The State contends that the Grant payments caused sales of EXPAREL at the recipient institutions to increase during the time period of December 1, 2012, through April 30, 2015.

F. As a result of the Covered Conduct, the State alleges that Pacira knowingly submitted or caused to be submitted false or fraudulent claims for EXPAREL to the State's Medicaid Program.

G. This Agreement is neither an admission of facts, liability, or wrongdoing by Pacira, nor a concession by the State that its allegations are not well founded. Pacira expressly denies the allegations and contentions of the State and the Relator, including the contention that it knowingly submitted false claims to the State's Medicaid Program.

H. 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. Pacira 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 \$3,500,000.00 plus accrued interest as set forth below (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) Pacira shall pay to the United States the sum of \$2,811,370.17, of which \$1,405,685.09 is restitution, plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$1,505,000.00, consisting of \$688,629.83 for the Medicaid Participating States pursuant to the State Settlement Agreements (as defined below in sub-paragraph (c)) and \$816,370.17 for the United States pursuant to the Federal Settlement Agreement. Pacira shall pay to the Medicaid Participating States the sum of \$688,629.83 plus accrued interest on that amount of 1.875% per annum commencing on December 17, 2019, and continuing 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”), 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 and immediately deposited by electronic funds transfer to the New York State Attorney General’s National Global Settlement Account pursuant to written instructions to be provided from the state negotiating team (the “State Team”) to counsel for Pacira. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III.1. (d) below.

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

(d) The total portion of the amount paid by Pacira in settlement for the Covered Conduct for the State is \$179,152.69, 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 \$79,536.63 plus applicable interest (the “State Amount”), of which \$39,768.32 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 Pacira absent written agreement between counsel for Pacira and the State Team to extend the time period for the State to execute 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 Pacira in state or federal courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator’s share, agrees to pay the Relator the amount of \$14,714.28 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. Further, contingent upon receipt of the State Amount, the State shall consent to Relator’s dismissal of the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Pacira set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Pacira, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the “Pacira Released Entities”), from any civil or administrative monetary claim 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, including, but not limited to, under the State Medicaid false claims statute and common law theories of fraud, payment by mistake, unjust enrichment, and breach of contract.

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 Pacira 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) 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. Pacira 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.

6. In consideration of the obligations of the State set forth in this Agreement, the Pacira 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 Pacira 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 Pacira 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 Pacira 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.

8. Pacira 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. Pacira 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.

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

11. 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.

12. 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.

13. 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.

14. In addition to all other payments and responsibilities under this Agreement, Pacira agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Pacira 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 State Settlement Agreements, or as otherwise agreed by the Parties.

15. 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.

16. The undersigned Pacira 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.

17. 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.

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

19. 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.

20. 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.

21. 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.

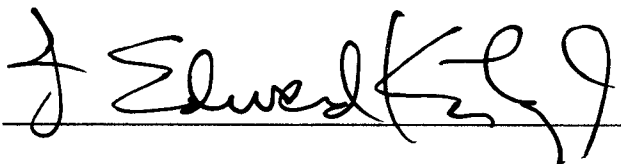
State of North Carolina

By:  Dated: 5/15/2020

Dave Richard
Name

Deputy Secretary, NC Medicaid
Title

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

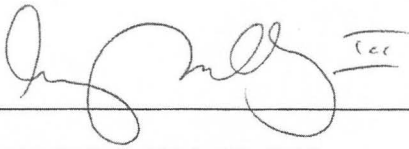
By:  Dated: 5-18-20

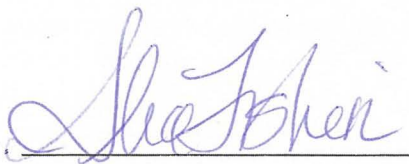
F. Edward Kirby, Jr.
Name

Director, Medicaid Investigations Division
Title

Office of the Attorney General
Organization

PACIRA PHARMACEUTICALS, INC.

By:  _____ Dated: July 17, 2020
ANTHONY MOLLOY, ESQ.
General Counsel of Pacira Pharmaceuticals, Inc.

By:  _____ Dated: 7/22/20
ALICE S. FISHER, ESQ.
BENJAMIN NAFTALIS, ESQ.
Latham & Watkins LLP

CHRISTOPHER PORRINO, ESQ.
SCOTT B. MCBRIDE, ESQ.
Lowenstein Sandler LLP

Counsel for Pacira Pharmaceuticals, Inc.