

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, (collectively, the “United States”), OraPharma, Inc. (“OraPharma”), and Megan Rumble (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. OraPharma is a Delaware corporation with its principal place of business in Bridgewater, New Jersey. OraPharma sells products for oral health, including Arestin, a sustained release antibiotic that is locally administered by dental providers as an adjunct to treatment for periodontal disease. In 2012, Valeant Pharmaceuticals International, a predecessor subsidiary of Bausch Health Companies Inc. (“Bausch”) acquired OraPharma. OraPharma now operates as a subsidiary of Bausch.

B. On April 26, 2019, Relator filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Megan Rumble v. OraPharma, Inc. & Valeant Pharmaceuticals North America LLC*, No. 19-cv-10998, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”).

C. The United States contends that OraPharma submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).

D. OraPharma admits, acknowledges, and accepts responsibility for the following facts. OraPharma sells an oral antibiotic called Arestin, which is an FDA-approved locally administered antibiotic for the treatment of adult periodontitis. During the period of June 2012 through December 2020, OraPharma employed account managers to promote Arestin to dental

practices. Certain account managers practiced as dental hygienists prior to working at OraPharma. Following their retention as account managers by OraPharma, some of these dental hygienists worked occasionally in a dental office or offices in their assigned sales territories but did not disclose in certain instances this occasional hygiene practice to OraPharma as required under the company's conflicts-of-interest policies. These account managers may have received or were eligible to receive incentive compensation for Arestin prescriptions that they may have recommended to Medicare beneficiaries when the account managers were performing dental hygienist duties in a dental office—i.e., while operating outside the scope of their employment with OraPharma. The conduct described in this paragraph is hereinafter referred to as the “Covered Conduct.”

E. The United States contends that the payments of incentive compensation to account managers for any prescriptions reimbursed by Medicare in the offices where the account managers practiced as dental hygienists violate the AKS and thereby caused false claims for prescriptions of Arestin to be submitted to Medicare in violation of the FCA.

F. With the exception of the facts described in the Covered Conduct, OraPharma expressly denies the allegations of the Relator as set forth in the Civil Action.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. OraPharma shall pay to the United States One Hundred Thousand Dollars (\$100,000), of which \$50,000 is restitution, plus interest accruing at an annual rate of 4% from October 5, 2022, continuing until and including the day of payment (“Settlement Amount”), no

later than thirty (30) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the District of Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$17,000 to Relator by electronic funds transfer (Relator's Share).

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases OraPharma, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors, and assigns (collectively, "the OraPharma Corporate Releasees") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0; Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 5 below, and upon the United States' receipt of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases the OraPharma Corporate Releasees, together with other legal entities directly or indirectly controlled by any of the OraPharma Corporate Releasees, together with their current and former officers, directors, employees, agents, and attorneys; and the predecessors, successors, transferees, and assigns of any of them from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and from any and all claims for relief, actions, rights, causes of

actions, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character, or nature whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator, her heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including, but not limited to, Relator's claims pursuant to 31 U.S.C. § 3730(d) for attorneys' fees and costs, and any other liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action. Relator acknowledges that she may discover facts or law different from, or in addition to, the facts or law that she knows or believes to be true with respect to the claims released in this Agreement and agrees nonetheless, that this Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

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

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;

- g. Any liability for failure to deliver goods or services due; and
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action. Relator and OraPharma have entered into a separate agreement that resolve Relator's claims for attorneys' fees, expenses, and costs under 31 U.S.C. § 3730(d) relating to the Civil Action.

7. OraPharma waives and shall not assert any defenses OraPharma may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. OraPharma fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that OraPharma has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and

servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

9. OraPharma fully and finally releases Relator and her heirs, successors, attorneys, agents, and assigns, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that OraPharma has asserted, could have asserted, or may assert in the future against Relator, her heirs, successors, attorneys, agents, and assigns related to the Covered Conduct and Relator's investigation and prosecution thereof.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and OraPharma agrees not to resubmit to any Medicare or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

11. OraPharma agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of OraPharma, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) OraPharma's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in

connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement; and
- (5) the payment OraPharma makes to the United States pursuant to this Agreement and any payments that OraPharma may make to Relator, including costs and attorneys' fees

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by OraPharma, and OraPharma shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by OraPharma or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: OraPharma further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by OraPharma or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the

inclusion of the Unallowable Costs. OraPharma agrees that the United States, at a minimum, shall be entitled to recoup from OraPharma any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by OraPharma or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on OraPharma or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine OraPharma's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

12. OraPharma agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, OraPharma shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. OraPharma further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.



13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 3, 4, and Paragraph 14 (waiver for beneficiaries paragraph), below.

14. OraPharma agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

15. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1) as follows:

(a.) The Stipulation of Dismissal shall be with prejudice to the United States' and Relator's claims against the Defendants in the Civil Action<sup>1</sup> as to the Covered Conduct; and

(b.) The Stipulation of Dismissal shall be without prejudice to the United States, and with prejudice as to Relator, as to all other claims against the Defendants in the Civil Action.

16. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

18. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

---

<sup>1</sup> Defendant Valeant Pharmaceuticals North America LLC is now known as Bausch Health US, LLC.

19. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

20. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

21. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

22. This Agreement is binding on OraPharma's successors, transferees, heirs, and assigns.

23. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: 2/6/2023

BY: LINDSEY ROSS Digitally signed by LINDSEY ROSS  
Date: 2023.02.06 12:27:42 -05'00'

LINDSEY ROSS  
CHARLES WEINOGRA  
Assistant United States Attorneys  
United States' Attorney's Office  
District of Massachusetts

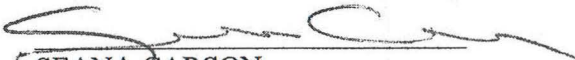
DATED: 02/01/2023

BY: *Lisa M. Re*


LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**ORAPHARMA, INC. - DEFENDANT**

DATED: Feb 2, 2023

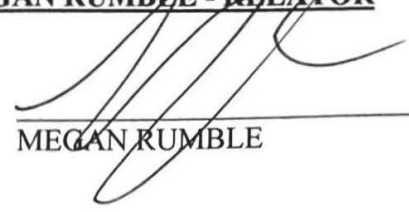
BY:   
SEANA CARSON  
Executive Vice President, General Counsel  
Bausch Health Companies Inc.

DATED: 2/6/23

BY:   
MATTHEW O'CONNOR  
NICOLE CHANDONNET  
Covington and Burling LLP  
Counsel for OraPharma, Inc.

**MEGAN RUMBLE - RELATOR**

DATED: 2/3/23

BY:   
\_\_\_\_\_  
MEGAN RUMBLE

DATED: \_\_\_\_\_


BY: \_\_\_\_\_  
ERIKA KELTON  
EMILY STABLE  
Philips & Cohen  
Counsel for Megan Rumble

**MEGAN RUMBLE - RELATOR**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
MEGAN RUMBLE

DATED: February 2, 2023

BY:   
\_\_\_\_\_  
ERIKA KELTON  
EMILY STABILE  
Philips & Cohen  
Counsel for Megan Rumble