UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

vs.

VINTAGE PHARMACEUTICALS, LLC, *d/b/a* QUALITEST PHARMACEUTICALS; GENERICS INTERNATIONAL (US), INC., *d/b/a* QUALITEST PHARMACEUTICALS; GENERICS BIDCO I, LLC, *d/b/a* QUALITEST PHARMACEUTICALS; GENERICS BIDCO II, LLC, *d/b/a* QUALITEST PHARMACEUTICALS; GENERICS INTERNATIONAL (US PARENT), INC.; GENERICS INTERNATIONAL (US HOLDCO), INC.; GENERICS INTERNATIONAL (US MIDCO), INC.; ENDO HEALTH SOLUTIONS INC., *f/k/a* ENDO PHARMACEUTICALS HOLDINGS, INC.; and ENDO PHARMACEUTICALS INC.,

Defendants.

13 Civ. 1506 (DLC)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

This proposed Stipulation and Order of Settlement and Dismissal (the "Stipulation") is entered into by and among the United States (the "United States" or the "Government"), defendants Vintage Pharmaceuticals, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US), Inc., *d/b/a* Qualitest Pharmaceuticals; Generics Bidco I, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics Bidco II, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US Parent), Inc.; Generics International (US Holdco), Inc.; Generics International (US Midco), Inc.; Endo Health Solutions Inc., *f/k/a* Endo Pharmaceuticals Holdings, Inc.; and Endo Pharmaceuticals Inc. (collectively, "Qualitest" or the "Defendants"), and the *qui tam* relator Stephan Porter ("Relator") (together with the Government and the Defendants, the "Settling Parties"), through their authorized representatives.

RECITALS

WHEREAS, Defendants are engaged in the manufacturing and distribution of generic drugs in the United States;

WHEREAS, from in or about October 2007 to August 2013, certain Defendants manufactured and distributed chewable multivitamin fluoride supplement tablets ("Qualitest Fluoride Tablets") in several doses in the United States;

WHEREAS, Defendants knew that federal healthcare programs, including Medicaid (established under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5) and the Federal Employees Health Benefits Program administered by the Office of Personnel Management (the "FEHBP"), paid claims submitted by pharmacies for dispensing Qualitest Fluoride Tablets to patients who were beneficiaries covered by those federal healthcare programs;

WHEREAS, on March 6, 2013, Relator filed a *qui tam* complaint in the above-captioned action (the "Action") pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), and on or about May 10, 2014, filed an amended complaint alleging that Defendants and/or their corporate affiliates had violated the FCA by causing the submission of false claims to federal healthcare programs relating to the Qualitest Fluoride Tablets;

WHEREAS, on December 15, 2015, the Government intervened in the Action and submitted a Complaint-in-Intervention (the "U.S. Complaint");

WHEREAS, the U.S. Complaint alleges that, from in or about October 2007 to in or about August 2013, Defendants violated the FCA by marketing, selling, and distributing Qualitest Fluoride Tablets that contained less than 50% of the fluoride ion indicated in the labels and, thereby, caused the submissions of more than hundreds of thousands of false claims to Medicaid and FEHBP (the "Covered Conduct");

WHEREAS, the Settling Parties have agreed on a full and final mutually agreeable resolution of their claims (except for the Relator's claims for reasonable attorney's fees and costs from Defendants);

AND WHEREAS, Defendants also intend to enter into settlement agreements with various states to resolve potential liability arising under those states' laws (the "State Settlement Agreements");

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants consent to this Court's exercise of personal jurisdiction over each of them with respect to this action.

2. Defendants admit, acknowledge, and accept responsibility for the following facts:

   a. As stated in guidelines issued jointly in 1994 by the American Dental Association, the American Academy of Pediatrics, and the American Academy of Pediatric Dentistry Pediatricians (the "ADA-AAP Guidelines"), dentists and other healthcare providers prescribe fluoride supplements to children under age 16 to prevent dental caries, *i.e.*, tooth decay.

   b. The ADA-AAP Guidelines recommended that children living in areas where the water is not fluoridated, or is insufficiently fluoridated, be prescribed fluoride supplements containing fluoride ion in the amount of 0.25 mg/day, 0.5 mg/day, or 1.0 mg/day, depending on the age of the child and the level of local water fluoridation, to prevent dental caries.

   c. From in or about 2007 to July 2013, certain Defendants, operating as Qualitest Pharmaceuticals or Vintage Pharmaceuticals, manufactured and sold fluoride supplement products in chewable tablet form with multivitamins.

   d. Qualitest Fluoride Tablets could only be dispensed subject to a prescription.

   e. State Medicaid programs covered Qualitest Fluoride Tablets dispensed to Medicaid-eligible children. Further, defendants knew that Medicaid was a significant source of coverage for Qualitest Fluoride Tablets because defendants regularly paid rebates for these products to Medicaid agencies.

   f. The product labeling for Qualitest Fluoride Tablets included dosage information, which stated the supplements contained 1.0 mg, 0.5 mg, or

0.25 mg of fluoride, respectively. The Qualitest Fluoride Tablets product labeling also referenced the ADA-AAP Guidelines and stated that one of its 1.0 mg, 0.5 mg, and 0.25 mg tablets, respectively, should be taken daily by children who, according to the ADA-AAP Guidelines, should receive 1.0 mg, 0.5 mg, and 0.25 mg, respectively, of fluoride ion per day.

g. Defendants used sodium fluoride (chemically, 2.2 mg of sodium fluoride contains 1 mg of fluoride ion) as an ingredient to manufacture Qualitest Fluoride Tablets.

h. Instead of using 2.2 mg of sodium fluoride as input to manufacture the 1 mg Qualitest Fluoride Tablets, Defendants used only 1 mg of sodium fluoride. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg tablet, Defendants used 0.5 mg of sodium fluoride and 0.25 of sodium fluoride, respectively.

i. The Qualitest Fluoride Tablets did not therefore contain 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion; rather, the 1.0 mg Qualitest Fluoride Tablet contained approximately 0.44 mg of fluoride ion, the 0.5 mg Qualitest Fluoride Tablet contained approximately 0.22 mg of fluoride ion, and the 0.25 mg Qualitest Fluoride Tablet contained approximately 0.11 mg of fluoride ion.

j. As a result, children that were prescribed Qualitest Fluoride Tablets in accordance with the recommendations of the ADA-AAP Guidelines (taking into account the pertinent variables including fluoridation of drinking water and age) and consumed one Qualitest Fluoride Tablet per day, as the product labeling instructed, received in any given tablet approximately 44% of the fluoride ion recommended by the ADA-AAP Guidelines.

3. Defendants agree to pay the United States, no later than fourteen business days after the Effective Date of this Stipulation, the sum of twenty-two million, four hundred forty-four thousand, six hundred eighty-one dollars and seventy-three cents ($22,444,681.73) (the "Federal Settlement Amount"), plus interest compounded annually at the rate of 2% accruing from September 14, 2015. Defendants shall make this payment by electronic funds transfer pursuant to written instructions from the United States Attorney's Office for the Southern District of New York.

4. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Federal Settlement Amount, the United States releases the Defendants, their parents, subsidiaries, and all of their current and former officers, directors, employees, shareholders, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under the FCA; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, fraud, and negligent misrepresentation.

5. Notwithstanding the releases given in paragraph 4 of this Stipulation, or any other term of this Stipulation, the following claims 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 Stipulation, any administrative liability, including mandatory or permissive exclusion from Federal health care programs and mandatory or permissive debarment;

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 Stipulation;

6. Conditioned upon Defendants' full payment of the Federal Settlement Amount, the Relator, for himself and his heirs, successors, attorneys, agents, and assigns, fully and finally releases, waives and forever discharges Defendants together with their current and former parent corporations, current, former, and future affiliates, direct and indirect subsidiaries, brother or sister corporations, divisions, transferees, and the predecessors, successors, and assigns of any of them and their current or former owners, directors, officers and employees, representatives, servants, agents, and attorneys, individually and collectively, from any and all manner of claims,

proceedings, liens, and causes of action of any kind or description that the Relator has against the Defendants related to the Relator's allegations in the Action. Provided, however, that, neither the Relator's release in this paragraph nor any other term of this Stipulation affects in any manner any claim of the United States against the Defendants or any other person or entity except to the extent that such claim is expressly released by the United States in Paragraph 4 above. Further provided that nothing in this Stipulation releases or shall be deemed to release the Relator's claims for his reasonable expenses and attorneys' fees and costs from the Defendants pursuant to 31 U.S.C. § 3730(d) and analogous state law provisions.

7. Conditioned upon the United States receiving the Federal Settlement Amount from Defendants, the United States shall pay $4,713,383.16 (the "Federal Relator's Share") , plus 21% of the interest accrued under Paragraph 2, to the Relator within a reasonable time by electronic funds transfer.

8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation but agree and confirm that this Stipulation 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 Federal Relator's Share, Relator and his 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 Action or under 31 U.S.C. § 3730 and from any claims to a share of the proceeds of this Stipulation and/or the Action.

9. Defendants waive and shall not assert any defenses they 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Stipulation constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have 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 and the United States' investigation and prosecution thereof.

11. Defendants fully and finally release the Relator from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

12. The Federal 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), FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor, FEHBP carrier or payer, 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.

13. Defendants agree 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. §§ 1395-1395kkk-1 and 1396-

1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of X, its present or former officers, directors, employees, shareholders, and agents in connection with:

i. the matters covered by this Stipulation;

ii. the United States' audit(s) and civil investigation(s) of the matters covered by this Stipulation;

iii. Defendants' 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 Stipulation (including attorney's fees);

iv. the negotiation and performance of this Stipulation;

v. the payment Defendants make to the United States pursuant to this Stipulation and any payments that Defendants may make to states pursuant to the State Settlement Agreements or to Relator, including costs and attorneys' fees; and

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

b. *Future Treatment of Unallowable Costs*: Unallowable Costs shall be separately determined and accounted for by Defendants and Defendants 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 Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. *Treatment of Unallowable Costs Previously Submitted for Payment*: Defendants further agree that within 90 days of the Effective Date of this Stipulation they 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 Defendants or any of their 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. Defendants agree that the United States, at a minimum, shall be entitled to recoup from them 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 Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants or any of their subsidiaries' or affiliates' cost reports, cost statements, or information reports.

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

14. Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Stipulation 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. The Effective Date of this Stipulation is the date it is entered by the Court.

16. Subject to the exceptions set forth in this Stipulation, and in consideration of the Defendants' obligations in this Stipulation, conditioned upon Defendants' full payment of the Federal Settlement Amount, the U.S. Complaint is dismissed with prejudice.

17. This Stipulation is binding on the Defendants' successors, transferees, heirs, and assigns and on the Relator's successors, transferees, heirs, and assigns.

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

19. This Stipulation is intended to be for the benefit of the Settling Parties only. The Settling Parties do not release any claims against any other person or entity.

20. Except for the Relator's statutory claims for reasonable attorney's fees and costs under the FCA, each Settling Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation.

21. Each Settling Party and signatory to this Stipulation represents that it freely and voluntarily enters in to this Stipulation without any degree of duress or compulsion.

22. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

23. This Stipulation constitutes the complete agreement between the Settling Parties. This Stipulation may not be amended except by written consent of the Settling Parties.

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

FOR THE UNITED STATES

So ordered.

Dated: New York, New York
December 14, 2015

PREET BHARARA
United States Attorney for the
Southern District of New York

By: _____
LI YU
JEAN-DAVID BARNEA
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Counsel for the United States

December 14, 2015

FOR THE DEFENDANTS

Dated: Washington, D.C.
December 13, 2015

ARNOLD & PORTER LLP

By: _____

JONATHAN L. STERN
DAVID D. FAUVRE
555 Twelfth Street, NW
Washington, D.C. 20004
Counsel for the Defendants

Dated: Malvern, PA
December 11, 2015

ENDO PHARMACEUTICALS INC.

By: _____

RAJIV De SILVA
Chief Executive Officer

Dated: Malvern, PA
December 11, 2015

ENDO HEALTH SOLUTIONS INC.

By: _____

RAJIV De SILVA
Chief Executive Officer

Dated: Malvern, PA
December 11, 2015

VINTAGE PHARMACEUTICALS, LLC

By: _____

RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS INTERNATIONAL (US), INC.

By: _____

RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS BIDCO I, LLC

By: _____

RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS BIDCO II, LLC

By: _____
RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS INTERNATIONAL (US PARENT), INC.

By: _____
RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS INTERNATIONAL (US HOLDCO), INC.

By: _____
RAJIV De SILVA

Dated: Malvern, PA
December 11, 2015

GENERICS INTERNATIONAL (US MIDCO), INC.

By: _____
RAJIV De SILVA

FOR THE RELATOR

Dated: West Palm Beach, Florida
December 8, 2015

McCABE RABIN, P.A.

By: _____
RYON M. McCABE
1601 Forum Place, Suite 505
West Palm Beach, Florida 33401
Counsel for Relator

Dated: December 7, 2015

_____
STEPHAN PORTER, Relator

* * *

SO ORDERED:

_____
Date

_____
HON. DENISE L. COTE
UNITED STATES DISTRICT JUDGE