

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 ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"), and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program, (collectively, the "United States"), Genentech, Inc. ("Genentech") and OSI Pharmaceuticals, LLC (together referred to as "Defendants"), and Brian Shields ("Relator") (hereinafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Genentech is a Delaware corporation with its principal place of business in South San Francisco. OSI Pharmaceuticals, Inc. was a Delaware corporation with its principal place of business in New York. In June 2010, OSI Pharmaceuticals, Inc. was acquired by Astellas US Holding, Inc. and, in March 2011, was converted to a Delaware limited liability company, OSI Pharmaceuticals LLC ("OSI"). Defendants manufactured, distributed, marketed, and promoted an oncology drug sold under the trade name Tarceva. Tarceva is approved by the U.S. Food and Drug Administration ("FDA") for multiple indications, including for the treatment of patients with "locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen."

B. On February 22, 2011, Relator filed a *qui tam* action pursuant to the provisions of the False Claims Act, 31 U.S.C. § 3730(b), and various state false claims

act statutes, in the United States District Court for the Northern District of California, Case Number CV 11-0822 MEJ, captioned *United States et al. ex rel. Brian Shields v. Genentech, Inc., et al.*, which was later amended on May 16, 2011 and again on September 29, 2011 (hereinafter “the Civil Action”).

C. The United States alleges that Defendants caused to be submitted claims for payment to the Medicare Program (“Medicare”), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program (“TRICARE”), 10 U.S.C. §§ 1071-1110b; the FEHBP, 5 U.S.C. §§ 8901-8914; and the Medicaid Program (“Medicaid”), 42 U.S.C. §§ 1396-1396w-5 (collectively the “Federal Health Care Programs”).

D. Tarceva treats non-small cell lung cancer (“NSCLC”) by targeting the epidermal growth factor receptor (“EGFR”) in cancerous cells. In 2013, the FDA approved Tarceva to treat patients with certain EGFR mutations “first line” - i.e., before the failure of at least one prior chemotherapy regimen. One measure of health status of NSCLC patients may be expressed in terms of performance status (“PS”) on the Eastern Cooperative Oncology Group (“ECOG”) performance status scale, with the healthiest patients classified as ECOG PS 0 or 1.

E. The United States contends that it has certain civil claims against Defendants arising from their distribution, marketing, and sale of Tarceva for NSCLC from 2006 through 2011:

Defendants made misleading representations to physicians and other health care providers about Tarceva’s effectiveness to treat certain NSCLC patients when there was little evidence to show that Tarceva was effective, unless the patients also had an EFGR

mutation or unless they had never smoked. As a result, Defendants knowingly caused false or fraudulent claims for Tarceva to be submitted to, or caused purchases by, Federal Health Care Programs for Tarceva to treat NSCLC, as a first line of therapy, in current or former smokers classified as ECOG PS 0 or 1 who did not have a known EFGR mutation, when such first line use was not approved by the FDA, was not a medically accepted indication as defined by 42 U.S.C. § 1396r-8(k)(6), or was not covered by the United States and state Medicaid programs. That conduct is referred to below as the "Covered Conduct."

F. Defendants have entered into, or will enter into, separate settlement agreements, described in Paragraph 1b below, with certain states in settlement of the Covered Conduct (hereinafter referred to as the "Medicaid State Settlement Agreements"). States with which Defendants execute a Medicaid State Settlement Agreement shall be referred to as "Medicaid Participating States."

G. This Settlement Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Defendants nor a concession by the United States that its claims are not well founded.

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

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants collectively shall pay to the United States and the Medicaid Participating States, the sum of Sixty-Seven Million Dollars (\$67,000,000.00), plus interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment (the "Settlement Amount"), pursuant to the following terms:

(a) Defendants collectively shall pay to the Medicaid Participating States the sum of \$4,355,000, plus interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment (the "Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the National Association of Medicaid Fraud Control Units ("NAMFCU") under the terms and conditions of the Medicaid State Settlement Agreements that Defendants will enter into with the Medicaid Participating States.

(b) Defendants collectively shall pay to the United States the sum of \$62,645,000, plus accrued interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment as set forth above (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer no later than seven (7) business days after the Effective Date of this Agreement pursuant to written instructions from the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the full Federal Settlement Amount from Defendants, and as soon as feasible after receipt, the United States shall pay \$10,649,650 to Relator by electronic funds transfer.

3. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases each Defendant together with its current and former direct and indirect parent corporation and limited liability companies ("Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their respective current and former owners; and the predecessors, successors, transferees and assigns of any of them, 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 creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to under 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or the common law theories for fraud, payment by mistake, and unjust enrichment.

4. Conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases each Defendant together with its current and former Parents; its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their respective current and former owners, officers, directors, employees, and agents, individually or collectively; and the predecessors, successors, transferees and assigns of

any of them from any civil monetary claim he has or may have 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 action, 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, his heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including but not limited to any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action, with the following exception: Relator and Relator's counsel do not release Defendants or related entities for Relator's claims for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d)(1); and/or retaliation claims under any state and/or federal law, including 31 U.S.C. § 3730(h) asserted in Counts III, IV, V, and VI in Relator's Second Amended False Claims Act Complaint.

5. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Defendants and/or their officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

6. DHA expressly reserves authority to exclude Defendants from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii).

7. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against Defendants from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).

8. Notwithstanding the releases given in Paragraphs 3 of this Agreement, or any other term of this Agreement, 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 Agreement, any administrative liability, 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 for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- h. Any liability of individuals; or
- i. Any liability for failure to deliver goods or services due.

9. Relator and his 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), and expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2 above, 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 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.

10. Each Defendant waives and shall not assert any defenses it 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. Nothing in this Paragraph or any other provision of this Agreement 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.

11. Each Defendant fully and finally releases 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 it 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.

12. In consideration of the obligations of the Relator set forth in this Agreement, each Defendant, together with its current and former Parents; its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions, fully and finally releases, waives, and forever discharges Relator and his heirs, successors, attorneys, agents, and assigns from any claims or allegations it has asserted or could have asserted arising from related to the initiation, investigation, and/or prosecution of the Civil Action by the Relator or his attorneys; provided, however, Defendants reserve any defenses or claims as to Relator's or Relator's counsel's claims for reasonable attorneys' fees, expenses and costs resulting from the Civil Action pursuant to 31 U.S.C. § 3730(d), or for retaliation claims under any state and/or federal law, including 31 U.S.C. § 3730(h) asserted in Counts III, IV, V, and VI in Relator's Second Amended False Claims Act Complaint, which are reserved pursuant to Paragraph 4 above.

13. 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), TRICARE or FEHBP carrier or payer, or any state payer (including any Medicaid contractor, fiscal intermediary, or carrier), related to the Covered Conduct; and each Defendant agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

14. Each Defendant 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of each Defendant, 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 and criminal investigation(s) of the matters covered by this Agreement;
- (3) that Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment each Defendant makes to the United States pursuant to this Agreement and any payments that Defendants may make to Relator, including costs and attorney's fees

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 each Defendant, and each Defendant 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 its or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Each Defendant 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 it 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. Each Defendant agrees that the United States, at a minimum, shall be entitled to recoup from it 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 either Defendant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on that Defendant 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 either Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. Each Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals not released in this Agreement, including, but not limited to, any administrative, civil, and/or criminal investigation regarding the marketing of Tarceva. More specifically, upon reasonable notice, each Defendant shall encourage, and agree 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. Each Defendant 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.

16. 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 17 (waiver for beneficiaries paragraph), below.

17. Each Defendant 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 its parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. Upon receipt of the payments described in Paragraph 1, above, the United States and the Relator shall within (7) business days make all necessary filings to seek dismissal of claims in the Civil Action against Defendants pursuant to Rule 41(a)(1). As to the United States, the action will be dismissed with prejudice as to the Covered Conduct released in the Settlement Agreement, and without prejudice as to any other claims. As to the Relator, the action will be dismissed with prejudice as to all claims except for those not released in Paragraph 4.

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

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

21. 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 Northern District of California. 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.

22. This Agreement constitutes the complete agreement among the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

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

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

25. This Agreement is binding on each Defendant's successors, transferees, heirs, and assigns.

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

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

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

THE UNITED STATES OF AMERICA

BRIAN J. STRETCH
United States Attorney for the
Northern District of California

DATED: 5.27.16

BY: 

ILA C. DEISS
Assistant United States Attorney

DATED:

BY: _____

JENNIFER CIHON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice


THE UNITED STATES OF AMERICA

BRIAN J. STRETCH
United States Attorney for the
Northern District of California

DATED:

BY: _____
ILA C. DEISS
Assistant United States Attorney

DATED: 6-3-16

BY:  _____
JENNIFER CIHON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/22/16

BY: Robert K. DeConti

ROBERT K. DECONTI
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

DATED:

BY: _____

BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED:

BY: _____

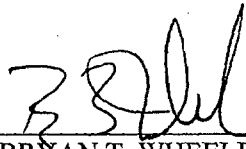
ALAN P. SPIELMAN
Assistant Director for
Federal Employee Insurance Operations
United States Office of Personnel Management

DATED:

BY: _____

ROBERT K. DECONTI
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

DATED: 4/8/14

BY:  _____

BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED:

BY: _____

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United States Office of Personnel Management

DATED:

BY: _____

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Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED:

BY: _____

BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED:

BY: Alan P. Spielman

ALAN P. SPIELMAN
Assistant Director of the
Federal Employee Insurance Operations
United States Office of Personnel Management

GENENTECH, INC.

DATED: 6/6/16

BY: 

PAUL E. KALB
DAVID ANDERSON
JOSHUA HILL

DATED: _____

BY: _____
HANNAH WILLIAMS

Counsel for Genentech, Inc.

OSI PHARMACEUTICALS, LLC

DATED: _____

BY: _____
MATTHEW O'CONNOR
GEOFFREY HOBART
SARAH FRANKLIN

Counsel for OSI Pharmaceuticals, LLC

DATED: _____

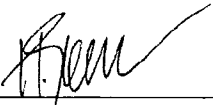
BY: _____
LINDA FRIEDMAN
Secretary, OSI Pharmaceuticals, LLC

GENENTECH, INC.

DATED: _____

BY: _____
PAUL E. KALB
DAVID ANDERSON
JOSHUA HILL

DATED: 6/6/16

BY:  _____
HANNAH WILLIAMS
Counsel for Genentech, Inc.

OSI PHARMACEUTICALS, LLC

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BY: _____
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SARAH FRANKLIN

Counsel for OSI Pharmaceuticals, LLC

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Counsel for Genentech, Inc.

OSI PHARMACEUTICALS, LLC

DATED: 6/6/16

BY: *Sarah Franklin*
MATTHEW O'CONNOR
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SARAH FRANKLIN

Counsel for OSI Pharmaceuticals, LLC

DATED: 6/6/16

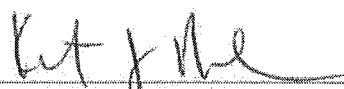
BY: *Linda Friedman*
LINDA FRIEDMAN
Secretary, OSI Pharmaceuticals, LLC

RELATOR

DATED: _____

BRIAN SHIELDS
Relator

DATED: 4/21/2016



KEN NOLAN
MARCELLA AUERBACH
JEB WHITE
Nolan Auerbach & White

Counsel for Relator

RELATOR

DATED: _____

4/25/2016



BRIAN SHIELDS
Relator

DATED: _____

KEN NOLAN
MARCELLA AUERBACH
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Nolan Auerbach & White

Counsel for Relator