

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice, the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), and the Defense Healthcare Agency (“DHA”), acting on behalf of the TRICARE program (collectively the “United States”), Daiichi Sankyo, Inc. (“Daiichi”), and Kathy Fragoules (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Daiichi is a Delaware Corporation with headquarters in Parsippany, New Jersey, that develops and markets pharmaceuticals, including Benicar and Benicar HCT, Welchol, Azor, and Tribenzor (collectively the “Drugs”).

B. On March 10, 2010, Kathy Fragoules filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Fragoules v. Daiichi Sankyo, Inc., et al.*, Civil Action No. 10.10420-NG, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). In her complaint, Relator alleges, among other things, that Daiichi caused false claims to be submitted to federal healthcare programs by providing inducements to physicians to prescribe the Drugs in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

C. The United States contends that Daiichi submitted or 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; the Medicaid Program (“Medicaid”), 42 U.S.C. §§ 1396-1396w-5; and the TRICARE Program, 10 U.S.C. §§ 1071-1110a; and

caused purchases by the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743 (collectively the “Federal Healthcare Programs”).

D. The United States contends that it has certain civil claims against Daiichi arising from Daiichi having caused false claims to be submitted to Federal Healthcare Programs by paying kickbacks to induce physicians to prescribe the Drugs. Specifically, the United States contends that the kickbacks took the form of honoraria payments, meals and other remuneration to physicians who participated, or supposedly participated, in Physician Opinion & Discussion programs (“PODs”) during the period from January 1, 2005, through March 31, 2011, and other speaker programs during the period from January 1, 2004, through February 4, 2011 (collectively, the “Speaker Programs”). The United States contends that the honoraria, meals and other remuneration were kickbacks, because Daiichi paid physicians who participated in the Speaker Programs even if, among other things: (1) the honoraria recipient spoke only to members of his or her own staff in his or her own office; (2) the physician participants in PODs took turns accepting a “speaker” honoraria for duplicative discussions; (3) the audience included the honoraria recipient’s spouse; (4) the honoraria recipient did not speak at all because the event was cancelled beforehand; and/or (5) the associated dinners were lavish and at times even exceeded Daiichi’s own internal cost limitations of \$140 per person. Daiichi’s Speaker Programs during the time periods specified in this Paragraph D are referred to in the Agreement as the “Covered Conduct.”

E. 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.

F. Daiichi has entered or will be entering into separate settlement agreements, described in Paragraph 1.b below (the “Medicaid State Settlement Agreements”), with certain states (the “Medicaid Participating States”) in settlement of the Covered Conduct.

To settle, compromise, and resolve the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Daiichi shall pay to the United States and the Medicaid Participating States \$39,015,770, plus interest at an annual rate of 2.125% from September 16, 2014, and continuing until and including the day of payment (collectively, 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 this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

a. Daiichi shall pay to the United States the sum of \$34,015,770 plus accrued interest as set forth above (“Federal Settlement Amount”). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States. Daiichi shall make this electronic funds transfer no later than seven business days after the Effective Date of this Agreement.

b. Daiichi shall pay the sum of \$5,000,000 plus accrued interest as set forth above (“Medicaid State Settlement Amount”) to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements that Daiichi has entered or will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Daiichi and as soon as feasible after receipt, the United States shall pay \$6,122,838.60 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer.

3. Daiichi agrees to pay Relator's attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in a separate agreement being entered into simultaneously with the execution of this Settlement Agreement.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Daiichi's full payment of the Settlement Amount, the United States releases Daiichi, together with its current and former parent corporations, the direct and indirect subsidiaries of Daiichi and its parent, and each of their brother or sister corporations, divisions, current or former owners, officers, directors, agents, and employees, and the successors 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. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. In consideration of the obligations of Daiichi in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and Daiichi, conditioned upon Daiichi's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Daiichi under 42 U.S.C. § 1320a-7a or 42

U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Daiichi from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of Daiichi set forth in this Agreement, conditioned upon Daiichi's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Daiichi under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude Daiichi from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraphs 4, 5, and 6 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 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 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.

8. 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 payment described in Paragraph 2, 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.

9. Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases Daiichi, together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, affiliates, divisions, current or former owners, officers, agents, insurers and employees, and the successors and assigns of any of them, from any liability to Relator arising from the filing of the Civil Action.

10. Daiichi waives and shall not assert any defenses Daiichi 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. Daiichi 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 Daiichi 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 and the United States' investigation and prosecution thereof.

12. Daiichi fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Daiichi has asserted, could have asserted, or may assert in the future against the Relator, related

to the allegations in the *qui tam* complaint filed in the Civil Action and the Relator's investigation and prosecution thereof.

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), Medicaid contractor, TRICARE payer or any state payer, related to the Covered Conduct; and Daiichi agrees not to resubmit to any Medicare contractor, Medicaid contractor, TRICARE 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. Daiichi 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 Daiichi, 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 or criminal investigation(s) of the matters covered by this Agreement;
- (3) Daiichi's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement;
- (5) the payment Daiichi makes to the United States pursuant to this Agreement and any payments that Daiichi may make to Relator, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
 - (ii) prepare and submit reports to the OIG-HHS

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). However, nothing in Paragraph 14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Daiichi.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Daiichi 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 Daiichi 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. Daiichi agrees that the United States, at a minimum, shall be entitled to recoup from Daiichi 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 Daiichi or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Daiichi 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 Daiichi's books and records to

determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. 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 Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Daiichi 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.

17. Upon the United States' receipt of the Federal Settlement Amount, 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), (a) dismissing with prejudice all claims concerning the Covered Conduct asserted on behalf of the United States against Daiichi in the Civil Action and (b) dismissing with prejudice to Relator and without prejudice to the United States all remaining claims against Daiichi in the Civil Action.

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

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

20. 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.

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

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

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

24. This Agreement is binding on Daiichi's successors, transferees, heirs, and assigns.

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

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

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

THE UNITED STATES OF AMERICA

DATED: 1/8/15

BY:



DOUGLAS ROSENTHAL
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/8/15

BY:



GREGG SHAPIRO
LISA ASIAP
GISELLE J. JOFFRE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 1/7/15

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: _____
PAUL J. HUTTER
General Counsel
Defense Health Agency
United States Department
of Defense

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: 1/8/2015

BY: *[Signature]*
for PAUL J. HUTTER
General Counsel
Defense Health Agency
United States Department
of Defense

DAIICHI SANKYO, INC.

DATED: 1-6-15

BY: Joseph K Keller
JOSEPH KENNETH KELLER
President, U.S. Commercial
Daiichi Sankyo, Inc.

DATED: 1-7-15

BY: Wendy C. Goldstein
WENDY C. GOLDSTEIN
SARAH K. DIFRANCESCA
Cooley LLP
Counsel for Daiichi Sankyo, Inc.

KATHY FRAGOULES

DATED: _____

BY: _____
KATHY FRAGOULES

DATED: _____

BY: _____
KEN NOLAN
MARCELLA AUERBACH
JEB WHITE
Nolan Auerbach & White P.L.
Counsel for Kathy Fragoules

DAIICHI SANKYO, INC.

DATED: _____

BY: _____

JOSEPH KENNETH KELLER
President, U.S. Commercial
Daiichi Sankyo, Inc.

DATED: _____

BY: _____

WENDY C. GOLDSTEIN
SARAH K. DIFRANCESCA
Cooley LLP
Counsel for Daiichi Sankyo, Inc.

KATHY FRAGOULES

DATED: 1/7/2015

BY: _____

Kathy Fragoules
KATHY FRAGOULES

DATED: 1/7/15

BY: _____

Ken Nolan
KEN NOLAN
MARCELLA AUERBACH
JEB WHITE
Nolan Auerbach & White P.L.
Counsel for Kathy Fragoules