

## STATE SETTLEMENT AGREEMENT

### PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Daiichi Sankyo, Inc. ("DSI"), hereinafter collectively referred to as "the Parties."

### RECITALS

The Parties agree as follows:

A. At all relevant times, DSI, a Delaware corporation with its principal place of business in Parsippany, New Jersey, distributed, marketed and/or sold pharmaceutical products in the United States, including the drugs Azor, Benicar/Benicar HCT, Tribenzor and Welchol (collectively, the "Subject Drugs").

B. On March 10, 2010, Kathleen Fragoules ("Relator") filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States of America, et al., ex. rel Fragoules v. Daiichi Sankyo, Inc., et. al*, Civil Action No. 10-10420-NG. The following four related *qui tams* actions were subsequently filed and thereafter transferred to the District of Massachusetts and administratively consolidated under the caption *United States ex. rel Fragoules v. Daiichi Sankyo, Inc.*, Civil Action No. 10-10420-FDS:

(i) *United States of America, et al., ex. rel Gramig and Andreozzi, v. Daiichi Sankyo, Inc., et. al* (Civil Action No. 10-cv-01599, USDC D.D.C.);

(ii) *United States of America, et al., ex. rel Reilly v. Daiichi-Sankyo, Inc.* (Civil Action No. 11-cv-0082, USDC W.D. Mich.);

(iii) *United States of America, et al., ex. rel Tun v. Daiichi Sankyo Co., Ltd., et. al*

(Civil Action No. 11-cv-10831, USDC D.Ma.); and

(iv) *United States of America, et al., ex. rel. Bozeman v. Daiichi-Sankyo Co., et. al* (Civil Action No. 2:13-cv-02781, USDC W.D. Tenn.).

These five consolidated cases will be collectively referred to as the "Civil Actions." The complaints filed in the Civil Actions alleged, *inter alia*, that DSI caused false claims to be submitted to government healthcare programs by providing inducements to physicians to prescribe the Subject Drugs in violation of the federal Anti-Kickback Statute (42 U.S.C. §§ 1320a-7b(b)) and analogous state statutes.

C. DSI has entered or will be entering into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the "United States."

D. The State contends DSI caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).

E. The State contends that it has certain civil claims against DSI arising from DSI having caused false claims to be submitted to state Medicaid programs by paying kickbacks to induce physicians to prescribe the Subject Drugs. Specifically, the State 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 State contends that the honoraria, meals and other remuneration were kickbacks because DSI

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 dinner was so lavish that its cost exceeded DSI's own internal cost limitation of \$140 per person. DSI's Programs and alleged conduct described in this Paragraph E are referred to in the Agreement as the "Covered Conduct."

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by DSI nor a concession by the State its claims are not well founded.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the Civil Actions and the above-cited claims, the Parties mutually desire to reach a full and final settlement as set forth below.

#### **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. DSI agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of \$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 the Federal Settlement Agreement and subject to the terms of this Agreement. The debt shall be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) DSI shall pay to the United States the principal sum of \$34,015,770, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) DSI shall pay to the Medicaid Participating States the sum of FIVE MILLION DOLLARS (\$5,000,000) plus accrued interest ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the sixty (60) day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), such written instructions to be delivered to counsel for DSI.

(c) DSI shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which DSI and the State Team have agreed,

or in a form otherwise agreed to by DSI and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to DSI's attorneys within sixty (60) days of receiving this Agreement. If this condition is not satisfied within sixty (60) days, DSI's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for DSI and the State Team to extend the sixty (60) day period.

(d) The total portion of the amount paid by DSI in settlement for the Covered Conduct for the State is \$281,073.97 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 \$99,429.75, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within sixty (60) days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by DSI absent written agreement between counsel for DSI and the State Team to extend the time period for executing this Agreement.

2. The State agrees to promptly dismiss with prejudice all state law claims which the State has the authority to dismiss currently pending against DSI in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of DSI set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release DSI, together with its current and former parent corporations, direct and indirect subsidiaries,

brother or sister corporations, affiliates, divisions, current and former owners, directors, officers, agents, insurers and employees, and the predecessors, successors, transferees, heirs, and assigns of any of them, individually and collectively (collectively, the "DSI Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including any DSI 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; (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 which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;

(f) any liability based upon obligations created by this Agreement;

(g) any administrative liability, including mandatory exclusions from the State's Medicaid program, unless explicitly stated in this Agreement;

(h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by DSI;

(i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

(j) any liability based on a failure to deliver goods or services due.

5. In consideration of the obligations of DSI set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") that DSI has entered or will be entering into with the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") in connection with this matter, and conditioned upon receipt by the State of its share of the State Medicaid Settlement Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against DSI for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against DSI in the event that DSI is excluded by the federal government, or for conduct and practices other than the Covered Conduct as reserved in Paragraph 4 above.

6. DSI 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 Constitution or the Excessive Fines Clause of the Eighth Amendment

of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, DSI waives and discharges the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which DSI has asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that DSI must pay to the State pursuant to Paragraph 1(d) above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and DSI agrees not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

9. DSI 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.

10. DSI expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

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

12. DSI agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice, DSI shall facilitate, and agree not to impair, the cooperation of its directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of DSI. Upon request, DSI agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in their possession, custody or control, concerning the Covered Conduct. DSI shall be responsible for all costs it may incur in complying with this paragraph.

13. 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.

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability against any other person or entity.

15. 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.

16. In addition to all other payments and responsibilities under this Agreement, DSI agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. DSI 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 Agreements, or as otherwise agreed by the Parties.

17. This terms of this Agreement are governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, 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.

18. The undersigned DSI 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.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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

21. 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.

22. 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.

STATE OF NORTH CAROLINA

By: Charles H. Hobgood  
CHARLES H. HOBGOOD  
Director, Medicaid Investigations Division  
Office of the Attorney General

Dated: 1/26/2015

By: [Signature]  
ROBIN G. CUMMINGS, M.D., Director  
Division of Medical Assistance

Dated: 1/26/15

**DAIICHI SANKYO, INC.**

By: Joseph K. Keller Dated: 3/4/2015

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

By: Wendy C. Goldstein Dated: 3/5/2015

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