

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of California ("the State") and Inspire Pharmaceuticals, Inc., hereinafter collectively referred to as "the Parties."

### II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Inspire is a Delaware corporation with its principal place of business at 1925 West Field Court, Lake Forest, IL 60045. Prior to its acquisition by Merck & Co., Inc., in May 2011, Inspire had its principal place of business in Durham, North Carolina, and engaged in the development, distribution, and sale of pharmaceutical and health care products, including its drug AzaSite® ("AzaSite"), throughout the United States.

B. On or about September 29, 2010, Jane Doe ("Relator") filed a *qui tam* action in the United States District Court for the Southern District of New York captioned *United States ex rel. Jane Doe v. Inspire Pharmaceuticals, Inc.*, 10 Civ. 7450 (LAP) ("the Civil Action"). The Civil Action contains multiple causes of action, among them claims pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3730(b), and several state False Claims Acts. The *qui tam* action named as plaintiffs the United States and the states of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North

Carolina, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia.

C. Inspire has entered 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 that Inspire caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)) for AzaSite.

E. The State contends that for the period of January 1, 2008 through September 30, 2011, it has certain civil and administrative causes of action against Inspire arising from false claims that were submitted to the State Medicaid programs specified below in this Paragraph E as a result of Inspire's off-label marketing of AzaSite for the treatment of blepharitis, a use not approved by the Food and Drug Administration ("FDA") and which was not a medically accepted indication as defined by 42 U.S.C. § 1396r-8(k)(6). Specifically, the State alleges that Inspire received FDA approval of AzaSite for the treatment of bacterial conjunctivitis (pink eye) and at no point received FDA approval of AzaSite for the treatment of blepharitis, an inflammation of the eyelash follicles along the edge of the eyelid. The State contends that although the treatment of blepharitis was not an FDA-approved use, Inspire nonetheless marketed AzaSite as a treatment for blepharitis and other indications with an inflammatory component, and as a result of the foregoing conduct, Inspire knowingly caused the submission of false and fraudulent claims for AzaSite to be submitted to the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396-1396w-5. The conduct described in this paragraph E is referred to as the Covered Conduct.

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Inspire, nor a concession by the State that its allegations are not well founded. Inspire expressly denies the allegations of the State as set forth herein and in the Civil Action.

G. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. 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. Inspire agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of \$5,960,809.57, as specifically delineated below, in civil damages, plus accrued interest on that amount of 2.250% per annum commencing on April 29, 2014, and continuing and including the day before payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt due and owing to the United States as set forth in the Federal Settlement Agreement referenced in paragraph 1(a) below, and a debt due and owing to the Medicaid Participating States on the Effective Date, subject to the terms of this Agreement, including the non-participating state deduction provision of sub-

paragraph (d) below. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Inspire shall pay to the United States the sum of \$4,938,573.77, plus accrued interest on that amount at a rate of 2.250% per annum commencing on April 29, 2014, ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Inspire shall pay to the Medicaid Participating States the sum of \$1,022,235.80, plus accrued interest on that amount at a rate of 2.250% per annum commencing on April 29, 2014 ("Medicaid State Settlement Amount"), no later than ten (10) business days after (i) the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below, or (ii) receipt of wiring instructions from the State Negotiating Team ("State Team"), whichever occurs later. 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 Team, which written instructions shall be delivered to counsel for Inspire.

(c) Inspire shall execute a State Settlement Agreement ("Agreement") with any State that executes such an Agreement in the form to which Inspire and the State Team have agreed, or in a form otherwise agreed to by Inspire and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to Inspire attorneys within 60 days of receiving this Agreement. If the Agreement is not returned to Inspire within 60 days, Inspire's offer to

resolve this matter with the individual State shall become null and void absent written agreement between counsel for Inspire and the State Team to extend the 60 day period.

(d) The total portion of the amount paid by Inspire in settlement for the Covered Conduct for the State is \$334,662.62, plus applicable interest, 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 \$174,906.42, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 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 Inspire absent written agreement between counsel for Inspire and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss that are currently pending against Inspire Pharmaceuticals, Inc. in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon the receipt of their respective State Amounts, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the Relator(s) the amount of \$34,981.30, plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Inspire 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

Inspire, its predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively (collectively, the "Inspire 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;

(c) any civil or administrative liability that any person or entity, including any 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) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

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

(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. The State expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Inspire and/or its officers, directors, and employees from the State Medicaid Program (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. Inspire waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct that are 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, Inspire 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 Inspire 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 State Amount 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 Inspire 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. Inspire 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. Inspire 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. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Inspire within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do in fact, constitute such a contemporaneous exchange.

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



12. Inspire agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice, Inspire shall facilitate, and agrees 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 Inspire. Upon request, Inspire agrees to furnish to the State complete and un-redacted 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. Inspire 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, Inspire agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Inspire 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 Agreement is governed by the laws of the State 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 Inspire 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 CALIFORNIA

On behalf of the California Attorney General's Office:

Original Signed By:  
By:  Stephen A. Franklin  
Deputy Attorney General  
Bureau of Medi-Cal Fraud and Elder Abuse  
California Department of Justice  
1455 Frazee Rd, Suite 315  
San Diego, CA 92108

Date: 4.7.15

On behalf of the California Medicaid Program:

Original Signed By:  
By: Jennifer Kent  
Director  
California Department of Health Care Services  
1501 Capitol Avenue, Suite 71.6001  
MS 0003  
Sacramento, CA 95814

Date: 4/1/15

Inspire

By: \_\_\_\_\_ Original Signed By: \_\_\_\_\_ Dated: 6/10/15

JOSEPH BONACCORSI  
Secretary  
Inspire Pharmaceuticals, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

By: \_\_\_\_\_ Original Signed By: \_\_\_\_\_ Dated: 6/11/15

JOHN T. BENTIVOGLIO  
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1440 New York Ave. N.W.  
Washington, D.C. 20005  
Counsel for Inspire Pharmaceuticals, Inc.

By: \_\_\_\_\_ Original Signed By: \_\_\_\_\_ Dated: 6/11/15

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