

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (“Agreement”) is entered into between *qui tam* relator Donald Galmines, the Commonwealth of Massachusetts (“the State”) and Novartis Pharmaceuticals Corporation (“Novartis”), hereinafter collectively referred to as “the Parties.”

II. PREAMBLE

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

A. At all relevant times, Novartis, a Delaware corporation headquartered in East Hanover, New Jersey, distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name Elidel®.

B. On July 21, 2006, Mr. Galmines filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and the false claims act of the State. The operative fourth amended complaint was filed on March 13, 2015 and is captioned *United States et al. ex rel. Donald R. Galmines v. Novartis Pharmaceuticals Corporation*, Civil Action No. 06-3213. This case is referred to below as “the Civil Action.” In May 2009, the United States declined to intervene in the Civil Action. In October 2011, the states of Delaware, Hawaii, Illinois, Massachusetts, Michigan, Nevada, Tennessee and Virginia and the District of Columbia declined to intervene. The Relator is currently pursuing claims under the state laws of Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Tennessee and Virginia.

C. Novartis will enter into a separate civil settlement agreement with Mr. Galmines and the United States of America, covering claims brought by Relator on behalf of the United States (the “Federal Settlement Agreement”).

D. Mr. Galmines and the State contend that Novartis caused claims for payment to be submitted to the State’s Medicaid Program, 42 U.S.C. §§ 1396-1396(v).

E. The State contends that it has certain civil and administrative causes of action against Novartis for allegedly engaging in the following conduct (the “Covered Conduct”):

From February 1, 2002 to April 30, 2009, NPC: (1) knowingly marketed and sold Elidel for use with children under the age of 2 and first line use, uses that were not FDA-approved, and for which the United States and state Medicaid Programs paid claims for Elidel; and (2) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Elidel in violation of state laws. As a result of the foregoing conduct, NPC caused false or fraudulent claims to be submitted to or caused purchases by Medicaid, in violation of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.* and analogous state statutes.

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Novartis, nor a concession by Mr. Galmines or the State that their allegations are not well founded. Novartis expressly denies the allegations as set forth herein and in the Civil Action and denies that it engaged in any wrongful conduct.

G. Mr. Galmines also asserts claims for: (1) payment under the State’s False Claims Act of a share of the proceeds of this Settlement Agreement; and (2) reasonable attorneys’ fees, expenses, and costs under the State’s False Claims Act. The first of these claims is resolved by a separate agreement between Mr. Galmines and the State, and the

second of these claims will be resolved by a separate agreement between Mr. Galmines and Novartis, or through judicial resolution.

H. 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. Novartis agrees to pay to the United States and the Participating States (as defined in sub-paragraph (c) below), collectively, the sum of \$35,000,000, plus accrued interest on that amount of 2.125% per annum commencing on November 23, 2015 and continuing and including the Effective Date of the Federal Settlement Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Participating States, under the following terms and conditions:

(a) Novartis shall pay to the United States the sum of \$30,628,798.28 plus accrued interest on that amount ("Federal Settlement Amount"). The Federal

Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Novartis shall pay to the Participating States the sum of \$4,371,201.72, plus accrued interest on that amount (“Medicaid Participating State Settlement Amount”), no later than fourteen (14) business days after the last Participating State executes its State Settlement Agreement. 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 Participating States, which written instructions shall be delivered to counsel for Novartis.

(c) Novartis shall execute a State Settlement Agreement with each Participating State in the form to which Novartis, Mr. Galmines, and the Participating States have agreed, or in a form otherwise agreed to by Novartis, Mr. Galmines, and an individual State. The State shall constitute a Participating State provided this Agreement, or an Agreement in a form otherwise agreed to by Novartis, Mr. Galmines and the State, is fully executed by the State and delivered to counsel for Novartis within 45 days of the State’s receipt of this Agreement. If this condition is not satisfied within 45 days, Novartis’s offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Novartis and the State to extend the 45-day period.

(d) The total portion of the amount paid by Novartis in settlement for the Covered Conduct for the State’s Medicaid program is \$454,856.23, 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 \$267,016.87, plus applicable interest, if any (the "State Amount").

2. The State and Mr. Galmines agree that Relator Galmines shall dismiss with prejudice the claims he brought on behalf of the State in the Civil Action within five business days of payment by Novartis of the State's Settlement Amount.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Novartis set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid Participating State Settlement Amount, the State (on behalf of itself, its officers, agencies, and departments) agrees to release Novartis and its predecessors, current and former divisions, affiliates, parents, direct and indirect subsidiaries, successors and assigns, individually and collectively, from any civil or administrative monetary cause of action that the State has or may have for any claims submitted or caused to be submitted to the State Medicaid Program for 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 Novartis, 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 express or implied warranty claims or other claims for defective or deficient products and services provided by Novartis;

(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 Novartis set forth in this Agreement, and conditioned on receipt by the State of its share of the Medicaid Participating State 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 Novartis for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from

taking action against Novartis in the event that Novartis is excluded by the federal government, or for conduct and practices other than the Covered Conduct. The State Medicaid Fraud Control Unit further agrees to refrain from recommending, causing or attempting to cause any administrative action or sanction, including debarment, by any other government agency of the State for the Covered Conduct.

6. Novartis 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, Novartis waives and discharges the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Novartis has against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

8. Relator and Novartis agree that the releases they entered into with respect to each other, set out in the federal settlement agreement, extend fully to this settlement agreement as if those releases were restated here.

9. The amount that Novartis must pay to the State pursuant to Paragraph III.1. (d) above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and Novartis 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 to withdraw the appeal of or not to appeal or cause the appeal of any such denials of claims.

10. Novartis 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.

11. Novartis 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)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

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

13. Novartis agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement, stemming from the Covered Conduct. Upon reasonable notice, Novartis 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 Novartis. Upon request, Novartis 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. Novartis shall be responsible for all costs it may incur in complying with this paragraph.

14. 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.

15. 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.

16. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the Internal Revenue laws, Title 26 of the United States Code, or the State's revenue code.

17. This Agreement is governed by the laws of the State.

18. The undersigned Novartis 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.

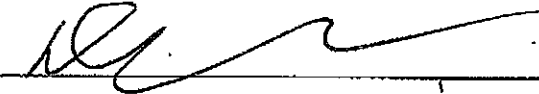
19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Electronic signatures or facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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.

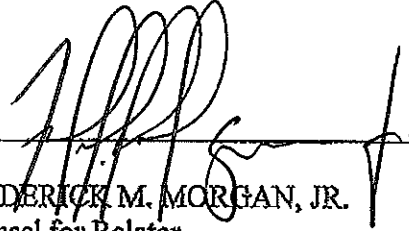
22. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

FOR MR. GALMINES

By: 

Dated: 9-23-16

DONALD E. GALMINES

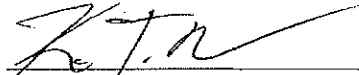
By: 

Dated: 23 SEPT '16

FREDERICK M. MORGAN, JR.
Counsel for Relator

For the Commonwealth of Massachusetts:

MAURA HEALEY, ATTORNEY GENERAL


By: 

Kevin Ready
Chief, Medicaid Fraud Division
One Ashburton Place, Room 1813
Boston, MA 02108

Dated: 7/28/16

For the Commonwealth of Massachusetts Medicaid Program:

**EXECUTIVE OFFICE OF HEALTH AND
HUMAN SERVICES, OFFICE OF MEDICAID**

By: 

Secretary Marylou Sudders
Executive Office of Health and Human Services
One Ashburton Place, 11th Floor
Boston, MA 02108

Dated: 20 July 2016

FOR NOVARTIS

By: Thomas N. Kendris Dated: 9/21/16

THOMAS N. KENDRIS
Vice President & General Counsel
Novartis Pharmaceuticals Corporation

By: Michael A. Rogoff Dated: 9/21/16

MICHAEL A. ROGOFF
Kaye Scholer LLP
Counsel for Novartis