

SETTLEMENT AGREEMENT AND RELEASE

Part I: Parties

This Settlement Agreement (the “Agreement”) is entered into by and between the State of Texas (“State”), Donald R. Galmines (“Relator”), (collectively referred to as “Plaintiffs”), and Novartis Pharmaceuticals Corporation (referred to as “Novartis” or “Defendant”) (the Plaintiffs and Defendant shall be collectively referred to as the “Parties”), through their authorized representatives.

Part II: Preamble

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

A. Defendant Novartis Pharmaceuticals Corporation is organized under the laws of New Jersey and has its principal place of business in East Hanover, New Jersey. At all times material to this civil action, Novartis transacted business in the State of Texas by, including but not limited to, selling and distributing to purchasers in the State of Texas the pharmaceutical product that is the subject of this action.

B. Plaintiffs contend that Defendant misrepresented and concealed information about the safety, efficacy, and appropriate use of Elidel[®] and improperly induced healthcare providers to prescribe Elidel[®], thereby committing unlawful acts in Texas. Accordingly, Plaintiffs contend that Defendant is liable pursuant to the Texas Medicaid Fraud Prevention Act (the “TMFPA,” Tex. Hum. Res. Code Chapter 36), the Texas Deceptive Trade Practices—Consumer Protection Act (the “DTPA,” Tex. Bus. & Com. Code § 17.41 *et seq.*), the Texas Anti-Kickback Statute (Tex. Hum. Res. Code §32.039 *et seq.*), the Texas Food, Drug and Cosmetic Act (“TFDCA,” Tex. Health & Safety Code §431.001 *et seq.*), and under common law.

C. Defendant’s alleged conduct referenced in paragraphs A and B is hereinafter referred to as the “Covered Conduct.” The Covered Conduct is expressly limited to (i) conduct

concerning Elidel[®] that occurred prior to the date of this Agreement and (ii) conduct giving rise to any cause of action that has been, could be, or may be asserted by the State of Texas or by Relator on behalf of the State of Texas for misrepresentations and concealment of information about the safety, efficacy, and appropriate use of Elidel[®], and the improper inducement of healthcare providers to prescribe Elidel[®], subject to additional limitations outlined below.

D. This Agreement is a compromise by the Parties of all matters in dispute between them arising from the Covered Conduct, including the related sealed lawsuit currently pending in Travis County (the “Texas Lawsuit”).

E. Defendant denies all of the Plaintiffs’ contentions, claims and allegations and denies it has any liability or wrongdoing related to such contentions, claims and allegations.

F. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these contentions, claims and allegations, and as a result of a mutual desire to settle their disputes, the Parties have reached a full and final settlement as set forth in this Agreement.

G. This Agreement does not constitute an admission of fault or liability by Defendant, nor does it constitute evidence of any liability or unlawful conduct on the part of Defendant, and the Plaintiffs will not urge or seek to admit this Agreement as evidence of any fault or liability of Defendant’s Released Parties in any investigation, administrative proceeding, or federal or state court or arbitration proceeding.

H. Plaintiffs represent to Defendant, subject only to the Relator’s rights as a *qui tam* plaintiff under applicable state and federal law to participate in this Agreement and to receive a percentage of the Settlement Amount, and to the rights possessed by the United States, that no interest in any claim herein released has been assigned by them to any third party.

I. The State has concluded that this settlement is in the public interest and is fair, adequate and reasonable under all the circumstances. Relator also agrees that the settlement is fair, adequate and reasonable.

Part III: Terms and Conditions

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

Incorporation of Representations

- 1) The foregoing Preamble is incorporated herein.

The Settlement Payment

2) Defendant agrees to pay the sum of **NINETEEN MILLION NINE HUNDRED THOUSAND DOLLARS (\$19,900,000)** (the "Settlement Amount") in full settlement of the Covered Conduct, including forfeiture and disgorgement of revenues, restitution, compensatory damages, penalties, and attorneys' fees and costs related to the Covered Conduct and any civil or administrative claim, action, suit or proceeding (including attorneys' fees, penalties, punitive damages, costs, and expenses of every kind and however denominated) the State and/or Relator have asserted, could assert, or may assert in the future for the Covered Conduct. This specifically includes all attorneys' fees relating to the Texas Lawsuit incurred by the State and Relator.

3) The State will allocate and distribute the Relator's share, attorneys' fees, and costs, as well as the United States' pro rata share of the net recovery, in accordance with state and federal law. The State agrees that the money paid by Defendant will be used, in part, to cover any and all claims the United States has as it pertains to the Covered Conduct. **In no way does entering into this Agreement entitle Defendant or its Counsel to direct or influence the**

allocation of the money paid to settle Plaintiffs' allegations against Defendant. Defendant expressly acknowledges that it is not entitled to direct or influence the manner in which the settlement amounts are allocated by Texas.

4) **THIS PARAGRAPH CONTAINS AN INDEMNITY AND HAS BEEN READ CAREFULLY BY RELATOR.** Defendant shall make payment of the Settlement Amount by wire transfer pursuant to written instructions to be supplied to Defendant's counsel by Raymond Winter, Chief, Civil Medicaid Fraud Division, at the Office of the Attorney General of Texas. The Parties will cooperate to exchange wiring and routing instructions so that such payment can be promptly made. **The Relator expressly INDEMNIFIES and holds Defendant's Released Parties harmless from and against any claims by persons or entities who have served as counsel for the Relator in connection with the claims released herein for: (1) attorneys' fees, costs, and expenses; or (2) any portion of the Settlement Amount.**

5) Defendant shall make payment to Plaintiffs, in accordance with Paragraph III(4) above, not later than 5:00 p.m. (Central Standard Time) of the seventh business day after this Agreement is signed by all parties and wire information has been provided to Defendant's counsel.

Accrual of Interest

6) The final settlement agreement shall be fully executed by all the necessary and authorized representatives and attorneys of Defendant within 45 days after receipt by Defendant's counsel of a proposed final settlement agreement from Texas, failing which the settlement amount shall bear interest at the post-judgment legal rate from the date of the signing of this term sheet until fully paid. In addition, to the extent that Texas requires more than 72 hours to respond to any of Defendant's comments or revisions to the final settlement agreement, the hours in excess of 72 hours will not be included in determining when 45 days have passed.

Plaintiffs: Release of Defendant

7) Subject to the exceptions in Paragraph III(11) below, in consideration of the obligations of Defendant set forth in this Agreement, and conditioned upon Defendant's payment in full of the Settlement Amount specified herein, Plaintiffs fully and finally release Defendant, its predecessors, successors and assigns as well as its respective current and former parents, subsidiaries, directors, officers, employees, agents, shareholders and attorneys (collectively, the "Defendant's Released Parties") from any civil or administrative claim, action, suit or proceeding (including attorneys' fees, penalties, punitive damages, costs, and expenses of every kind and however denominated) the State and/or Relator have asserted, could assert, or may assert in the future for the Covered Conduct. This specifically includes all attorneys' fees relating to the Texas Lawsuit incurred by the State and the Relator. The Office of the Attorney General of Texas shall not initiate or prosecute litigation against Defendant on behalf of the United States based on the Covered Conduct. **This agreement is not intended to release claims or causes of action unrelated to the Covered Conduct, and the agreement is not intended to release claims or causes of action pursued by Relator or Relator's Counsel based on any similar conduct by Defendant in states other than Texas. For example and without limitation, specifically excluded from the release are any and all claims relating to requests for payment submitted to entities other than the State of Texas (and Texas administrative agencies) that are or may be asserted by Relator on behalf of the United States and states other than Texas in the civil action known as *United States ex rel Galmines v. Novartis Pharmaceuticals Corporation*, Civil Action No. 2:06-cv-03213-GP, now pending before the United States District Court for the Eastern District of Pennsylvania, with the exception of any claims the Relator may have on behalf of the United States with respect to**

the federal share of Medicaid payments in Texas, which claims are specifically being released under this agreement.

8) In consideration of the obligations of Defendant set forth in this Agreement, conditioned upon Defendant's payment in full of the Settlement Amount specified herein, the State (on behalf of itself, its agents, agencies, employees, servants, attorneys and departments) agrees not to unseal the Texas Lawsuit and to refrain from instituting, recommending, directing or maintaining any administrative claim or any action seeking exclusion, suspension, or debarment from the VDP or any other Texas Medicaid program against Defendant's Released Parties for the Covered Conduct as it relates to the Texas Medicaid program, except as reserved in Paragraph III(11) below.

Defendant: Release of the State

9) Defendant fully and finally releases the State, its agents, agencies, employees, servants, attorneys and departments from any claims based on events occurring prior to the date of this Agreement (including attorneys' fees, costs, and expenses of every kind and however denominated) which Defendant has asserted, could assert, or may assert in the future against the State, its agents, agencies, employees, servants, attorneys and departments, related to the Covered Conduct and the Plaintiffs' investigation and prosecution thereof. This release shall not release any accounts receivable unrelated to the Covered Conduct due from the State, or any agency or instrumentality of the State. This agreement is not intended to release claims or causes of action unrelated to the Covered Conduct.

Defendant: Release of the Relator

10) Defendant fully and finally releases the Relator and his agents and attorneys from any claims based on events occurring prior to the date of this Agreement (including attorneys' fees, costs, and expenses of every kind and however denominated) which Defendant has

asserted, could assert, or may assert in the future against the Relator and his agents and attorneys, related to the Covered Conduct and the Plaintiffs' investigation and prosecution thereof. This agreement is not intended to release claims or causes of action unrelated to the Covered Conduct.

Limitations on Release

11) Notwithstanding any other terms of this Agreement, including the release provisions in Paragraphs III(7), (8), (9), and (10) above, specifically reserved and excluded from the scope and terms of this Agreement, and from the scope and terms of the releases, as to any entity or person (including Defendant), are any and all of the following:

- (a) Any claims based upon obligations created by the Agreement;
- (b) Any express or implied product or service warranty claims or other claims for defective or deficient products or services, including quality of goods and services by Defendant;
- (c) Any civil or administrative liability that any person or entity has or may have to individual consumers involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;
- (d) Any liability related to the alleged improper reporting of prices to the Texas Medicaid program;
- (e) Any civil or administrative liability that any person or entity, including the Defendant's Released Parties, has or may have to the State for state or federal antitrust violations;
- (f) The subrogation rights to claims for personal injury or property damage arising from usage of Elidel[®] by a participant in the Medicaid Program;
- (g) Any claims based on a failure to deliver products or services due;
- (h) Any claims arising from Defendant's obligation to report and/or to pay rebates to the State under any law or contract, including, but not limited to, under the provisions of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90");
- (i) Any claims that the Relator may have under any provision of 31 U.S.C.A. §§ 3729-3733 (the Federal False Claims Act), with the exception of any claims the Relator may have under the Federal False Claim Act with respect to the federal share of Medicaid payments in Texas, which claims are being released under this settlement; or
- (j) Any claims that the Relator may have under the *qui tam* provisions of the laws of any state other than Texas.

Corporate Integrity Agreement

12) Should Defendant enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services (“OIG”) relating to the Covered Conduct, Defendant acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the State.

No Waiver or Release of Claims Against Other Persons

13) This Agreement is intended to be solely for the benefit of the Parties and persons and entities released and, except as stated herein, the Parties do not by this instrument release any claims against any other person or entity, including any individual or entity that purchased drugs or pharmaceutical products from Defendant. No word, term, phrase or definition in this Agreement is or may be used for the benefit of any person, entity or litigant who is not a signatory to, or released by this Agreement.

Dismissal of Action

14) Within seven days of payment of the Settlement Amount, the Relator will execute a motion to dismiss and order (in the forms collectively attached hereto as **Exhibit A**) dismissing with prejudice the Texas Lawsuit against Defendant based on the Covered Conduct.

No Impairment or Creation of Rights

15) Nothing in this Agreement shall be construed to abrogate or alter any future obligation of Defendant pursuant to the law of the State.

No Waiver of Sovereign Immunity

16) Nothing in this Agreement shall be construed to create a waiver of the State’s Sovereign Immunity.

Exclusive Venue for Enforcement of Agreement

17) Any party shall be entitled to enforce the terms of this Agreement in the District Courts of Travis County, Texas, which shall have exclusive jurisdiction and venue over any such action.

Complete Agreement

18) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.

Costs

19) Except as noted in Paragraphs III(2) and III(3), each Party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

Choice of Law

20) This Agreement is governed by the laws of the State of Texas.

Notification

21) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

(a) State for all purposes:

Raymond C. Winter, Esq.
Chari L. Kelly, Esq.
Office of the Attorney General
Civil Medicaid Fraud Division
P. O. Box 12548
Austin, Texas 78711-2548

(b) Relator for all purposes:

Frederick M. Morgan, Esq.
Morgan Verkamp, LLC

700 Walnut Street
Cincinnati, Ohio 45202

(c) Defendant for all purposes:

Michael A. Rogoff
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022-3598

Richard L. Josephson
Baker Botts, LLP
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002-4995

No Duress

22) All parties represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

Authorization

23) The Parties have read the foregoing Agreement and accept and agree to the provisions contained herein and hereby have caused this Agreement to be signed as of the day and date adjacent to their respective signatures. The undersigned individuals signing this Agreement on behalf of Defendant represent(s) and warrant(s) that they are authorized by Defendant 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.

No Other Representations or Promises

24) The Parties represent and acknowledge that in entering into this Agreement they are not relying on any promises or representations other than those expressly set forth in this Agreement and its exhibits.

Counterparts

25) This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall be deemed to constitute one and the same Agreement. Facsimile or PDF signatures shall be valid signatures as of the date thereof.

Acts Necessary to Effectuate Agreement

26) Each Party agrees to perform such further acts and to execute and to deliver such further documents as may reasonably be necessary to carry out this Agreement.

Captions Are for Convenience Only

27) The bold-face paragraph captions in this Agreement are for convenience only and do not add to, detract from or change the substantive language or terms of this Agreement.

Effective Date

28) The Effective Date of this Agreement shall be the date upon which all of the Parties below have executed this Agreement.

Defendant

Novartis Pharmaceuticals Corporation

By: 

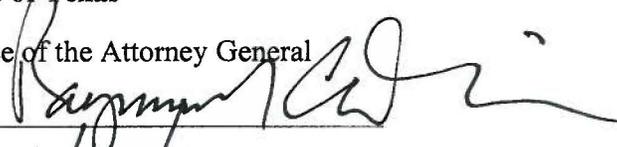
Date: 10/3/12

ANDRÉ WYSS

André Wyss, PRESIDENT,
NOVARTIS PHARMACEUTICALS CORPORATION
President, Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, New Jersey 07936

State of Texas

Office of the Attorney General

By: 

Date: 10/22/12

Raymond C. Winter
Chief, Civil Medicaid Fraud Division
Office of the Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

Texas Health & Human Services Commission

By: _____

Date: _____

Printed Name: _____

Title: _____

Relator, Donald R. Galmines

By: _____

Date: _____

Printed Name: Donald R. Galmines

Counsel for Relator

By: _____

Date: _____

Frederick M. Morgan, Jr.
Morgan Verkamp, LLC
700 Walnut Street
Cincinnati, Ohio 45202

Defendant

Novartis Pharmaceuticals Corporation

By: _____

Date: _____

Printed Name: _____

Title: _____

State of Texas

Office of the Attorney General

By: _____

Date: _____

Raymond C. Winter
Chief, Civil Medicaid Fraud Division
Office of the Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

Texas Health & Human Services Commission

By: Kyle M. Janek

Date: 10.19.12

Printed Name: Kyle M. Janek, M.D.

Title: Executive Commissioner, Texas Health and Human Services Commission

Relator, Donald R. Galmines

By: _____

Date: _____

Printed Name: Donald R. Galmines

Counsel for Relator

By: _____

Date: _____

Frederick M. Morgan, Jr.
Morgan Verkamp, LLC
700 Walnut Street
Cincinnati, Ohio 45202

Texas Health & Human Services Commission

By: _____

Date: _____

Printed Name: _____

Title: _____

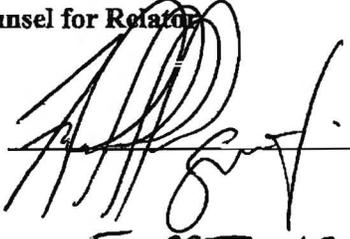
Relator, Donald R. Galmines

By: Donald R. Galmines

Date: 10/5/12

Printed Name: Donald R. Galmines

Counsel for Relator

By: 

Date: 5 OCT 12

Frederick M. Morgan, Jr.

Morgan Verkamp, LLC

700 Walnut Street

Cincinnati, Ohio 45202