SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice, and the Defense Health Agency (DHA), acting on behalf of the TRICARE Program, Relator Donald Galmines and Novartis Pharmaceuticals Corporation ("Novartis"), collectively referred to as "the Parties," through their authorized representatives.

RECITALS

A. Novartis is a Delaware corporation headquartered in East Hanover, New Jersey. Novartis is a manufacturer and supplier of prescription drugs. At all relevant times, Novartis marketed a drug sold under the trade name of 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). The operative fourth amended complaint was filed on March 13, 2015 and is captioned *United States, States of Hawaii, Illinois, Indiana, Louisiana, Michigan, Tennessee, and the Commonwealths of Massachusetts and Virginia 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.

C. Novartis will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the "State Settlement Agreements"), with certain states in settlement of the Covered Conduct, as that term is defined herein. States with which Novartis executes a State Settlement Agreement in the form to which Novartis and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or

in a form otherwise agreed to by Novartis and an individual State, shall be defined as "Participating States."

D. The United States contends that Novartis caused claims for payment for Elidel to be submitted to the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid") and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE").

E. The United States contends that it has certain civil claims against Novartis for allegedly engaging in the following conduct:

> From February 1, 2002 to April 30, 2009, Novartis 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 were not covered by TRICARE or Medicaid. As a result of the foregoing conduct, Novartis caused false or fraudulent claims to be submitted to or caused purchases by TRICARE and Medicaid (hereinafter referred to as the "Covered Conduct").

F. This Agreement is neither an admission of liability by Novartis nor a concession by Mr. Galmines or the United States that Mr. Galmines' claims, or the claims of the United States, are not well founded. Novartis denies the allegations as set forth herein and in the Civil Action.

G. Mr. Galmines claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to his reasonable expenses, attorneys' fees, and costs. The first of these claims, for a share of the proceeds of this Agreement, is resolved in this Agreement. The second, for attorneys' fees, expenses, and costs, is neither addressed nor resolved by this Agreement, and is reserved by Relator and Novartis for resolution by subsequent agreement.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Novartis shall pay to the United States and the Participating States, collectively, the sum of $35,000,000 (thirty-five million dollars) (hereinafter the "Settlement Amount") and interest on the Settlement Amount at the rate of 2.125% per annum from November 23, 2015. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Participating States. The debt shall be discharged by payments to the United States and Participating States as follows:

a. Novartis shall pay to the United States the sum of $30,628,798.28 plus interest thereon at a rate of 2.125% per annum from November 23, 2015 to and including the Effective Date of this Agreement (hereinafter the "Federal Settlement Amount"). Novartis shall pay the Federal Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States by the Effective Date of this Agreement. Novartis shall make this electronic funds transfer no later than ten calendar days after the Effective Date of this Agreement.

b. Novartis shall pay to the Participating States the sum of $4,371,201.72 plus interest thereon at a rate of 2.125% per annum from November 23, 2015 to and including the Effective Date of this Agreement (hereinafter the "State Settlement Amount"). The State Settlement Amount shall be paid by electronic funds transfer in accordance with written instructions to be provided by the NAMFCU Negotiating Team pursuant to the terms and conditions agreed upon by Novartis and the NAMFCU Negotiating Team and as set forth in the State Settlement Agreements that Novartis will enter into with the Participating States.

2. Conditioned upon the United States receiving the Settlement Amount from Novartis and as soon as feasible after receipt, the United States shall pay $8,882,351.50 to Relator by electronic funds transfer.

3. Subject to the exception in Paragraph 7 below (concerning excluded claims), and conditioned upon Novartis' full payment of the Settlement Amount, Mr. Galmines, for himself and for his heirs, successors, attorneys, agents, and assigns, or any other person or entity acting on his behalf or asserting his rights, fully and finally releases, waives and forever discharges Novartis and its predecessors, current and former divisions, affiliates, parents, direct and indirect subsidiaries, successors and assigns and their current and former directors, officers, and employees, agents and attorneys, individual and collectively, from all liability, claims, demands, claims for relief, actions, rights, causes of action whatsoever, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character or nature whatsoever, existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, or that Mr. Galmines or his heirs, successors, attorneys, agents, or assigns would have standing to bring, whether or not related to the Civil Action, with the exception of Mr. Galmines' claims for attorneys' fees and costs under 31 U.S.C. § 3730(d), which are being resolved by separate agreement and are expressly not covered by this Agreement. Subject to this exception, this Paragraph is intended to be interpreted as a general release on behalf of Mr. Galmines, who warrants and represents that he has not assigned or transferred any of his claims to any person, entity, or thing.

4. Novartis fully and finally releases Mr. Galmines and his heirs, assigns, attorneys and agents from any claims, including any and all claims, claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages, punitive damages, costs and expenses of any kind, character or nature whatsoever existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, or otherwise that they, their heirs, successors, attorneys, agents and assigns otherwise have standing to bring. This Paragraph is intended to be interpreted as a general release, and Novartis warrants and represents that it has not assigned or transferred any of its claims to any person, entity, or thing.

5. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Novartis' payment of the Settlement Amount, the United States agrees to release Novartis and its predecessors, current and former divisions, parent corporations, direct and indirect subsidiaries, and the corporate successors and assigns, individually and collectively, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

6. In consideration of the obligations of Novartis set forth in this Agreement, and conditioned upon Novartis'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 Novartis and its predecessors, current and former divisions, parent corporations, direct and indirect subsidiaries, and the corporate successors and assigns, individually and collectively, under 32 C.F.R. § 199.9 for the Covered Conduct, except as

reserved in this Paragraph and in Paragraph 7 (concerning excluded claims), below. DHA expressly reserves authority to exclude Novartis and its predecessors, current and former divisions, parent corporations, direct and indirect subsidiaries, and the corporate successors and assigns from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), 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 any other term of this Agreement, including the release in Paragraphs 3, 5 and 6, 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 or permissive 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 of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct and the United States' investigation and prosecution thereof.

8. Novartis waives and shall not assert any defenses it 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.

9. Novartis fully and finally releases the United States, and its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Novartis has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct.

10. Novartis 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 Novartis, their 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 and any criminal investigations of the matters covered by this Agreement;

(3) Novartis' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigations in connection with the matters covered by this Agreement (including attorney's fees);

(4) Novartis' negotiation and performance of this Agreement; and

(5) the payment Novartis makes to the United States pursuant to this Agreement and any payments that Novartis may make to or on account of Mr. Galmines, including costs and attorney's fees;

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).

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Novartis 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 Novartis 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. Novartis agrees that the United States, at a minimum, shall be entitled to recoup from Novartis 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.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Novartis' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

11. Relator and his 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 his 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.

12. 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 13, below.

13. Novartis 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.

14. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file a Stipulation of Dismissal in the form agreed to by the Parties and attached as Exhibit A, wherein the United States shall dismiss with prejudice all claims as to the Covered Conduct, and without prejudice as to all other claims in the Civil Action; Mr. Galmines shall dismiss with prejudice all claims in the Civil Action.

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

16. 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 Eastern District of Pennsylvania. 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.

17. Except for Relator's claims for reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d), each of the Parties shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

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

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

21. This Agreement is binding on Novartis' successors, transferees, heirs, and assigns.

22. This Agreement is binding on Mr. Galmines' successors, transferees, heirs, and assigns.

23. All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

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

FOR DEFENDANT NOVARTIS

DATED: 7/26/16

Thomas N. Kendris
Vice President & General Counsel
Novartis Pharmaceuticals Corporation

DATED: 7/27/16 BY:

KAYE SCHOLER LLP

Michael A. Rogoff
250 West 55th Street
New York, New York 10019-9710

Counsel for Novartis

FOR RELATOR DONALD E. GALMINES

DATED: 7-26-16 BY: _____
Donald E. Galmines

DATED: 26 JULY 2016 BY: _____
Frederick M. Morgan, Jr.
Counsel for Donald E. Galmines

FOR THE UNITED STATES OF AMERICA

DATED: 7/27/10 BY: _____

Alan Gale
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/28/16 BY: _____
Zane David Memeger
United States Attorney

DATED: 7/28/16 BY: _____
Margaret L. Hutchinson
Assistant United States Attorney
Chief, Civil Division

DATED: 7/28/16 BY: _____
Gregory B. David
Assistant United States Attorney

DATED: July 25, 2016

BY: TROFF.ERIK.ANDREW.1138681005 Digitally signed by TROFF.ERIK.ANDREW.1138681005 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=DHA, cn=TROFF.ERIK.ANDREW.1138681005 Date: 2016.07.25 15:06:22 -06'00'

Erik A. Troff
Acting General Counsel
Defense Health Agency
United States Department of Defense

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
***ex rel.* DONALD R. GALMINES, *et al.*,**	)	**CIVIL ACTION**
Plaintiffs	)	
	)	
v.	)	
	)	
NOVARTIS PHARMACEUTICALS	)	**No. 06-3213**
CORPORATION,	)	
Defendant.	)	

JOINT STIPULATION OF PARTIAL DISMISSAL

Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure and the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b)(1), and in accordance with the terms and conditions of the Settlement Agreement ("Agreement") among the United States of America, acting through the United States Department of Justice, the Defense Health Agency, acting on behalf of the TRICARE Program, Relator Donald Galmines, on his own behalf, on behalf of the United States, and Novartis Pharmaceuticals Corporation ("Novartis"), collectively referred to as "the Parties," through their authorized representatives, the Parties hereby stipulate to the entry of an order that:

1. The Civil Action shall be:

    a. dismissed with prejudice as to the Relator's claims in the Civil Action, pursuant to and consistent with the terms and conditions of the Agreement;

b. dismissed with prejudice as to the United States' claims as to the Covered Conduct, pursuant to and consistent with the terms and conditions of the Agreement; and

c. dismissed without prejudice as to the United States all claims not for the Covered Conduct, pursuant to and consistent with the terms and conditions of the Agreement.

2. The Court will retain jurisdiction over any disputes that may arise regarding compliance with the Agreement.

3. This dismissal does not include: (1) Relator's state law claims on behalf of the States of Hawaii, Illinois, Indiana, Louisiana, Michigan, Tennessee, and the Commonwealths of Massachusetts and Virginia; (2) Relator's claims for a statutory share of the amounts paid by Novartis to the States of Hawaii, Illinois, Indiana, Louisiana, Michigan, Tennessee, and the Commonwealths of Massachusetts and Virginia; or (3) Relator's claims against Novartis for attorney's fees, costs and expenses under 31 U.S.C. § 3730(d) and analogous state law provisions.

4. A proposed order accompanies this joint stipulation.

Respectfully submitted,

For Relator Donald Galmines:

FREDERICK M. MORGAN, JR.
Morgan Verkamp, LLC
35 East Seventh Street, Suite 600
Cincinnati, Ohio 45202
Tel. (513) 651-4400
Fax (513) 651-4405
rmorgan@morganverkamp.com

For Novartis Pharmaceuticals Corporation:

MICHAEL A. ROGOFF
Kaye Scholer LLP
250 West 55th Street
New York, NY 10019-9710
Tel. (212) 836-7684
Fax (212) 836-6615
michael.rogoff@kayescholer.com

For the United States:

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General

ZANE DAVID MEMEGER
United States Attorney

MARGARET L. HUTCHINSON
Assistant United States Attorney

Chief, Civil Division

GREGORY B. DAVID
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
TEL: (215) 861-8521
FAX: (215) 861-8618
gregory.david@usdoj.gov

MICHAEL D. GRANSTON
JAMIE A. YAVELBERG
ALAN S. GALE
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, DC 20044
TEL: (202) 307-6296
FAX: (202) 616-3085
alan.gale@usdoj.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
***ex rel.* DONALD R. GALMINES, *et al.*,**	)	**CIVIL ACTION**
Plaintiffs	)	
	)	
v.	)	
	)	
NOVARTIS PHARMACEUTICALS	)	**No. 06-3213**
CORPORATION,	)	
Defendant.	)	

ORDER OF PARTIAL DISMISSAL

Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure and the False Claims Act, 31 U.S.C. § 3730(b)(1), and in accordance with the terms and conditions of the Settlement Agreement ("Agreement") among the United States of America, acting through the United States Department of Justice, the Defense Health Agency, acting on behalf of the TRICARE Program, Relator Donald Galmines, on his own behalf and on behalf of the United States, and Novartis Pharmaceuticals Corporation ("Novartis"), collectively referred to as "the Parties," the Parties filed a Joint Stipulation of Partial Dismissal as to claims in this action.

Upon due consideration of the Joint Stipulation of Partial Dismissal and the papers on file in this action, **IT IS HEREBY ORDERED** that:

1. the Civil Action shall be:
    a. dismissed with prejudice as to the Relator's claims in the Civil Action, pursuant to and consistent with the terms and conditions of the Agreement;
    b. dismissed with prejudice as to the United States' claims as to the Covered Conduct, pursuant to and consistent with the terms and conditions of the

Agreement; and

c. dismissed without prejudice as to the United States as to all claims not for the Covered Conduct, pursuant to and consistent with the terms and conditions of the Agreement.

2. This Order of Partial Dismissal does not include: (1) Relator's state law claims on behalf of the States of Hawaii, Illinois, Indiana, Louisiana, Michigan, Tennessee, and the Commonwealths of Massachusetts and Virginia; (2) Relator's claims for a statutory share of the amounts paid by Novartis to the States of Hawaii, Illinois, Indiana, Louisiana, Michigan, Tennessee, and the Commonwealths of Massachusetts and Virginia; or (3) Relator's claims against Novartis for attorney's fees, costs and expenses under 31 U.S.C. § 3730(d) and analogous state law provisions.

3. The Court will retain jurisdiction over any disputes that may arise regarding compliance with the Agreement.

SO ORDERED.

BY THE COURT:

_____

Hon. Gene E.K. Pratter
United States District Judge