

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), the TRICARE Management Activity (“TMA”), and the United States Office of Personnel Management (“OPM”) (collectively the “United States”); Eisai, Inc. (“Eisai”); and Lee R. Chartock, M.D. (“Relator”) (hereafter referred to as “the Parties”), through their authorized representatives.

II. PREAMBLE

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

A. Eisai is a Delaware corporation headquartered in Woodcliff Lake, New Jersey. At all relevant times, Eisai distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Zonegran. Eisai acquired the North American interests in Zonegran on or around April 27, 2004. The Food and Drug Administration (“FDA”) approved first-time generic formulations of Zonegran on December 22, 2005.

B. On or about July 16, 2004, Lee R. Chartock, M.D. (“Relator”) filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States, et al. ex rel. Lee R. Chartock, M.D. v. Elan Corporation, PLC, et al.*, Civil Action No. 04-11594-RWZ (hereinafter the “Civil Action”).

C. Eisai has entered into or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Eisai executes a Medicaid State Settlement Agreement in the form to which Eisai and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form otherwise agreed to by Eisai and an individual State, shall be defined as “Medicaid Participating States.”

D. The United States alleges that Eisai caused to be submitted claims for payment for Zonegran to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. The United States further alleges that Eisai caused claims for payment for Zonegran to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1109; and the Federal Employees Health Benefits Program (“FEHBP”), 5 U.S.C. §§ 8901-8914; and caused purchases of Zonegran by the Department of Veterans Affairs (“DVA”) (collectively, the “other Federal Health Care Programs”).

E. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 2, below, against Eisai for engaging in the following conduct:

During the period from April 27, 2004 through December 31, 2005, Eisai knowingly marketed, sold and promoted Zonegran for certain uses that were not approved by the Food and Drug Administration (“FDA”) (i.e., “unapproved uses”). Certain of these unapproved uses were not medically accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) (hereinafter “medically accepted indications”) for which the United States and state Medicaid programs provided coverage for Zonegran. As a result of the foregoing conduct, Eisai knowingly

caused false or fraudulent claims for Zonegran to be submitted to, or caused purchases by, Medicaid, the TRICARE and FEHB Programs, and the Veterans' Administration. (Hereinafter referred to as the "Covered Conduct.")

F. The United States also contends that it has certain administrative claims against Eisai, as specified in Paragraphs 4-6 below, for engaging in the Covered Conduct.

G. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts nor liability by Eisai nor a concession by the United States that its claims are not well founded. Eisai expressly denies the allegations of the United States and the Relator set forth herein and in the Civil Action and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by Eisai.

H. To avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, 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 in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Eisai agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of eleven million dollars (\$11,000,000), plus interest at the rate of 2.875% per annum from December 15, 2009 and continuing until and including the day before payment is made (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 this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

a. Eisai shall pay to the United States the sum of \$6,341,751 plus accrued interest (“Federal Settlement Amount”). The Federal Settlement Amount shall consist of \$6,341,751, plus interest accrued on this amount at the rate of 2.875% per annum from December 15, 2009, continuing until and including the day before payment is made. The Federal Settlement Amount shall be paid no later than seven (7) business days after this Agreement is fully executed by the Parties and delivered to Eisai’s attorneys. The Federal Settlement Amount shall be paid by electronic funds transfer account pursuant to written instructions from the United States.

b. Eisai shall pay to the Medicaid Participating States the sum of \$4,658,249 plus accrued interest (“Medicaid State Settlement Amount”). The Medicaid State Settlement Amount shall consist of the sum of \$4,658,249 plus interest accrued thereon at a rate of 2.875% per annum from December 15, 2009, continuing until and including the day before payment is made. The Medicaid State Settlement Amount shall be paid no later than seven (7) business days after this Agreement is fully executed by the Parties and delivered to Eisai’s

attorneys. The Medicaid State Settlement Amount shall be paid by electronic funds transfer to an interest bearing account pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Eisai will enter into with the Medicaid Participating States.

c. Contingent upon the United States receiving the Federal Settlement Amount from Eisai, and as soon as feasible after receipt, the United States agrees to pay \$1,141,515, plus accrued interest, to Relator by electronic funds transfer.

2. Subject to the exceptions in Paragraph 7 (concerning excluded claims), below, in consideration of the obligations of Eisai in this Agreement, conditioned upon Eisai's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Eisai, its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, and their current and former directors, officers, and employees from any civil or administrative monetary claim the United States has or may have 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; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d) and common law claims for fraud, payment by mistake, disgorgement and unjust enrichment.

3. Subject to the exceptions in Paragraph 7 (concerning excluded claims), below, in consideration of the obligations of Eisai in this Agreement, and conditioned upon Eisai's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release Eisai, its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, and their current and former directors, officers, and employees from any civil monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; provided, however, that Relator does not release Eisai for any claims under 31 U.S.C. § 3730(d).

4. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion of Eisai and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (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).

5. In consideration of the obligations of Eisai set forth in this Agreement, conditioned upon Eisai's full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against Eisai, its predecessors, its current and former divisions, parents, subsidiaries, successors and assigns, and their current and former directors, officers and employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude Eisai under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B),

and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA 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.

6. OPM expressly reserves all rights to institute, direct or to maintain any administrative action seeking debarment against Eisai and/or its officers, directors, and employees from the FEHBP under 5 U.S.C. § 8092(b) (mandatory debarment), or (c) and (d) (permissive debarment).

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Eisai and Relator) are the following claims of the United States:

- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Any civil, criminal, or administrative liability of any other defendant to this action;
- d. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- e. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- f. Any liability based upon such obligations as are created by this Agreement;

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; or

h. Any liability for failure to deliver items or services due.

8. Relator and his respective heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and 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), and, conditioned upon receipt of Relator's share, Relator, for himself individually, and for his heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of the Civil Action as to Eisai; and from any other claims for a share of the Settlement Amount; and in full settlement of any claims Relator may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. Conditioned upon receipt of the payment described in Paragraph 1(c), above, Relator, for himself, and for his respective heirs, successors, attorneys, agents, and assigns, hereby fully and finally releases and forever discharges Eisai, its predecessors, and its divisions, parents, subsidiaries, related entities, officers, directors, trustees, agents, servants, employees, representatives, attorneys, consultants, successors, heirs, executors, administrators, and assigns, individually and collectively, current or former (collectively, the "Eisai Entities"), from any and all claims, claims for relief, actions, rights, causes of action, 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, known or unknown, fixed or contingent, in law or in equity, in contract or tort, or under any state or federal statute or regulation or otherwise that Relator has standing to bring, which Relator may now have or claim to have against the Eisai Entities, arising in any way out of or connected in any way with the facts, claims, and circumstances alleged in, arising under, or arising from the filing of, the Civil Action, or from any other past activities and actions of the Eisai Entities, except that Relator does not release the Eisai Entities for any claims that Relator has for reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d). Relator does not release the Medicaid Participating States from any claims that Relator has for a share of any settlement or judgment obtained by the Medicaid Participating States concerning the Covered Conduct.

10. Eisai 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.

11. Eisai fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every

kind and however denominated) that Eisai has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution of the Civil Action.

12. In consideration of the obligations of the Relator set forth in this Agreement, Eisai, on behalf of itself and the Eisai Entities, fully and finally releases, waives and forever discharges the Relator and his respective heirs, successors, assigns, agents and attorneys from any claims Eisai has asserted or could have asserted, against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution of the Civil Action, except as they relate to a claim by Relator for reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, Medicaid, TRICARE, or FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Eisai agrees not to resubmit to any Medicare carrier or intermediary or Medicaid, TRICARE, or FEHBP carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

14. Eisai agrees to the following:

a. Unallowable Costs Defined: That all costs (as defined in the Federal Acquisition Regulations ("FAR"), 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Eisai, its present

or former officers, directors, employees, shareholders, and agents in connection with the following shall be “Unallowable Costs” on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

- (1) the matters covered by this Agreement;
- (2) the United States’ audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Eisai’s investigation, defense, and any corrective actions undertaken in response to the United States’ audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys’ fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payments Eisai makes to the United States or any State pursuant to this Agreement, or the Medicaid State Settlement Agreements and any payments that Eisai may make to Relator.

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

c. Treatment of Unallowable Costs Previously Submitted for

Payment: Eisai 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 Eisai 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. Eisai agrees that the United States, at a minimum, shall be entitled to recoup from Eisai 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.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Eisai or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Eisai's or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

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

15. Eisai agrees to cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, Eisai shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Eisai agrees to furnish to the United States, upon reasonable request, complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or other agent.

16. 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 17 (waiver for beneficiaries paragraph), below or elsewhere in this Agreement. Defendant Elan Corporation, PLC is specifically excluded from this Agreement.

17. Eisai 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.

18. Eisai warrants that it has reviewed its financial situation and that it currently is 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 to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Eisai, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Eisai was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

19. Upon receipt of the payments described in Paragraph 1, above, the United States shall promptly sign and file in the Civil Action a Notice of Intervention and the United States and Relator shall file a Joint Stipulation of Dismissal with prejudice of the Civil Action as to the Eisai Entities consistent with the terms of this Agreement.

20. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

22. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the District of Massachusetts.

23. For purposes of construction, 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.

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

25. The individuals signing this Agreement on behalf of Eisai represent and warrant that they are authorized by Eisai to execute this Agreement. The individuals signing this Agreement on behalf of Relator represent and warrant that they are authorized by Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

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

27. This Agreement is binding on Eisai's successors, transferees, heirs, and assigns.

28. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

29. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

THE UNITED STATES OF AMERICA

TONY WEST
Assistant Attorney General

DATED: _____

BY: _____

JOYCE R. BRANDA
Director
BRIAN J. McCABE
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

CARMEN M. ORTIZ
United States Attorney, District of Massachusetts

DATED: _____

BY: _____

ANTON P. GIEDT
Assistant United States Attorney
Office of the United States Attorney
for the District of Massachusetts

DATED: _____

BY: _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of the Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: _____

BY: _____

GARY J. KRUMP
Deputy Assistant
Secretary for Acquisition and Material Management
United States Department of Veterans Affairs

DATED: _____

BY: _____

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
United States Office of Personnel Management

Eisai - DEFENDANT

Eisai, Inc.

DATED: 6/14/10 BY: 
J. SEDWICK SOLLERS III, Esquire
Counsel authorized to execute on behalf of Eisai

DATED: 6/14/10 BY: 
MARK A. JENSEN, Esquire
Counsel authorized to execute on behalf of Eisai

Lee R. Chartock, M.D. - RELATOR

DATED: 6/14/10 BY: Lee R. Chartock / RMT
LEE R. CHARTOCK, M.D.

DATED: 6/14/10 BY: Robert M. Thomas, Jr.
ROBERT M. THOMAS, JR.

DATED: 6/14/10 BY: Suzanne E. Durrell
SUZANNE E. DURRELL

DATED: 6/14/10 BY: Royston H. Delaney / by SRO
ROYSTON H. DELANEY
Counsel for Relator Lee R. Chartock, M.D.