STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of California ("the State"); and Warner Chilcott U.S. Sales LLC ("Warner Chilcott,"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

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

- A. Warner Chilcott is a for-profit limited liability company organized under the laws of Delaware with its principal place of business in Parsippany, New Jersey. Warner Chilcott distributed, marketed and sold pharmaceutical products in the United States, including drugs sold under the following trade names: Actonel®, Asacol®, Asacol HD®, Atelvia®, Doryx®, Enablex®, Estrace®, Loestrin 24 Fe®, and Lo Loestrin® (collectively, "the Subject Drugs"). In October 2013, Warner Chilcott plc, Warner Chilcott's indirect parent corporation, became a wholly-owned subsidiary of Actavis, plc.
- B. On October 25, 2010, a qui tam action was filed in the United States District Court for the District of Massachusetts captioned United States ex rel. Alexander, et al. v. Warner Chilcott plc, et al., No. 11-cv-10545-RGS (D. Mass.), pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) and various States' False Claims statutes. On April 22, 2013 Relators filed their Second Amended Complaint. On August 21,

2013 Relators filed their Third Amended Complaint. This qui tam action will be referred to collectively as the "Civil Action."

- C. On such date as may be determined by the Court, Warner Chilcott will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in <u>United States v. Warner Chilcott, U.S. Sales LLC</u>, Criminal Action No.[to be assigned] (D. Mass.) that will allege violations of 18 USC § 1347 (the "Federal Criminal Action").
- D. Warner Chilcott has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement).
- E. The State alleges that Warner Chilcott caused claims for payment for the Subject Drugs to be submitted to the Medicaid Program (Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5).
- F. The State alleges that it has certain civil and administrative causes of action against Warner Chilcott for engaging in the following conduct causing false or fraudulent claims to be submitted to the State's Medicaid program (the "Covered Conduct"):
 - 1. The State contends that during the period January 1, 2009, through March 31, 2013, Warner Chilcott knowingly offered and paid illegal remuneration to physicians throughout the United States, including in the State to induce them to prescribe the Subject Drugs to Medicaid beneficiaries, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. §

1320a-7b(b). The illegal remuneration consisted of payments, honoraria, meals, snacks, and gifts associated with medical education events, which included speaker programs, speaker training, dinners, lunches, receptions, preceptorships, and in-office programs. These events were used as a way to pay remuneration to physicians and other health care providers. The company required sales representatives to conduct a minimum number of medical education events, which often were held at up-scale restaurants, contained minimal or no educational component, and were instead used to gain a "competitive advantage" over competitors.

2. The State contends that during the period January 1, 2011, through March 31, 2013, Warner Chilcott assisted healthcare professionals with prior authorization requests, non-formulary exception requests, coverage determination requests, and appeals documentation throughout the United States, including to the State's Medicaid program, in order to ensure coverage and reimbursement of the drug Atelvia® and to overcome formulary restrictions that favored less expensive oral bisphosphonate drugs. Warner Chilcott personnel routinely completed the required prior authorization forms, including both paper and electronic versions, or coached healthcare professionals regarding the content to use on required forms, in many cases using information that was false, inaccurate, misleading, or of unknown application to the particular patient. Warner Chilcott also submitted prior authorization requests through www.covermymeds.com, a

web-based software application that allows health care professionals and pharmacists to submit prior authorization requests more efficiently. In particular, certain Warner Chilcott sales representatives posed as health care professionals in order to gain access to www.covermymeds.com that was otherwise not available to them, and thereafter they submitted numerous prior authorization requests for Atelvia[®], many of which contained information that was false, inaccurate, misleading, or of unknown application to the particular patient.

- 3. The State contends that during the period October 1, 2009, through March 31, 2013, Warner Chilcott assisted healthcare professionals with prior authorization requests, non-formulary exception requests, coverage determination requests, and appeals documentation to the New York State Medicaid program in order to ensure coverage and reimbursement of the drug Actonel® and to overcome formulary restrictions that favored less expensive oral bisphosphonate drugs. Warner Chilcott personnel routinely completed the required forms, including both paper and electronic versions, or coached healthcare professionals regarding the content to use on required forms, in many cases using information that was false, inaccurate, misleading, or of unknown application to the particular patient.
- 4. The State alleges that the acts described in paragraphs F1, F2 and F3 above caused false or fraudulent claims for the Subject Drugs to be submitted to the State Medicaid program.

- G. This Agreement is neither an admission of facts or liability by Warner Chilcott, nor a concession by the State that its allegations are not well founded. Warner Chilcott expressly denies the allegations of the State as set forth herein and in the Civil Action, and denies that it engaged in any wrongful conduct in connection with the Covered Conduct, except as to such admissions Warner Chilcott makes in connection with its guilty plea in the Federal Criminal Action referenced in Paragraph C above.
- 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:

Participating States (as that term is defined in sub-paragraph (c) below), collectively, the sum of \$102,060,000.00 plus interest at the rate of 1.875% per annum commencing on February 18, 2015, and continuing until and including the day payment is made under this Agreement (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 the Federal Settlement Agreement. This debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under

the following terms and conditions:

- (a) Warner Chilcott shall pay to the United States the sum of \$91,477,694.00, plus interest accrued thereon at the rate of 1.875% per annum commencing on February 18, 2015, continuing until and including the day payment is made ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.
- (b) Warner Chilcott shall pay to the Medicaid Participating States the sum of \$10,582,306.00, plus interest accrued thereon at the rate of 1.875% per annum commencing on February 18, 2015, continuing until and including the day payment is made ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) 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) the Court accepts the Fed. R. Crim. P. 11(c) (1) (C) guilty plea in the Federal Criminal Action and imposes the agreed-upon sentence, 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 Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Warner Chilcott.
- (c) Warner Chilcott shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Warner Chilcott and the State Team

have agreed, or in a form otherwise agreed to by Warner Chilcott and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Warner Chilcotts' attorneys within the period of 60 days immediately following the State's receipt of this Agreement. If this condition is not satisfied within 60 days Warner Chilcott's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Warner Chilcott and the State Team to extend the 60 day period.

- (d) The total portion of the amount paid by Warner Chilcott in settlement for the Covered Conduct for the State is \$5,464,992.71, 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 individual portion of the Medicaid State Settlement Amount allocated to the State under this Agreement is the sum of \$3,088,340.24, 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, plus applicable interest, shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Warner Chilcott absent written agreement between counsel for Warner Chilcott and the State Team to extend the time period for executing this Agreement.
- 2. The State agrees to promptly dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the Warner Chilcott Released Parties as defined in Paragraph 3 below in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. The State further agrees to dismiss without prejudice all other claims against the Warner

Chilcott Released Parties in the Civil Action. Contingent upon the receipt of its respective State Amount, the State, served with the Civil Action and liable to pay a Relator's share, agrees to pay the Relator(s) the amount of \$772,085.06, plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter(s) with the Relators in the Civil Action.

- 3. Subject to the exceptions in Paragraph 4 below, and in consideration of the obligations of Warner Chilcott set forth in this Agreement, conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release Warner Chilcott, together with its current and former direct and indirect parent corporations, and each of their current and former direct and indirect subsidiaries, brother and sister corporations, divisions, and affiliates; and each of their current and former owners, officers, directors, and employees; and the predecessors, successors, assigns, and transferees of any of them (collectively, the "Warner Chilcott Released Parties"), from any civil or administrative monetary claims or causes 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. The payment of the Medicaid State Settlement Amount fully discharges the Warner Chilcott Released Parties from any obligations to pay Medicaid restitution, Medicaid damages, Medicaid civil fines, and/or Medicaid civil penalties, to the State 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 any
 Released Parties, 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; or (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 expressed or implied warranty claims or other liability for defective or deficient products and services provided by Warner Chilcott;
- (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 items or services due.

(k) any claims set forth in State of California ex rel. Johnson, et al. v. Warner Chilcott PLC, et al., Case No. 2:14-cv-03249-DMG-JC (C.D. Cal.).

- 5. If Warner Chilcott's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Federal Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the State or Warner Chilcott. If either the State or Warner Chilcott exercises this option, which option shall be exercised by notifying all parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Warner Chilcott will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the State within 90 calendar days of rescission and that were not otherwise barred as of the Effective Date of this Agreement.
- 6. This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of the acceptance of Warner Chilcott's plea of guilty in the Federal Criminal Action, the State's Medicaid Fraud Control Unit agrees that it shall not further criminally investigate, prosecute, or refer for prosecution or criminal investigation to any agency, Warner Chilcott, its current and former direct and indirect parent corporations, and each of their current and former direct and indirect subsidiaries, brother and sister corporations, divisions, and affiliates for the Covered Conduct.

7. In compromise and settlement of the rights of OIG-HHS to exclude Warner Chilcott pursuant to 42 U.S.C. § 1320a-7(a)(1) based on an agreement to plead guilty to 18 U.S.C. §1347 (a felony) described in Paragraph C of the Preamble above, and pursuant to 42 U.S.C. § 1320a-7(b)(7) based upon the Covered Conduct described in Paragraph F of the Preamble above, Warner Chilcott agrees to be permanently excluded from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). The permanent exclusion shall become effective upon Warner Chilcott's sentencing in the Criminal Action.

Such exclusion shall have national effect. Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by Warner Chilcott in any capacity while Warner Chilcott is excluded. This payment prohibition applies to Warner Chilcott and all other individuals and entities (including, for example, anyone who employs or contracts with Warner Chilcott, and any hospital or other provider where Warner Chilcott provides services). The exclusion applies regardless of who submits the claim or other request for payment. Violation of the conditions of the exclusion may result in criminal prosecution and the imposition of civil monetary penalties and assessments. Warner Chilcott further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. Warner Chilcott waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court.

- 8. Warner Chilcott 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.
- 9. In consideration of the obligations of the State set forth in this Agreement, Warner Chilcott waives and discharges the State, its agencies, employees, and agents from any causes of action (including claims for attorneys' fees, costs, and expenses of every kind and however denominated) which Warner Chilcott has against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.
- 10. The amount that Warner Chilcott must pay to the State pursuant to Paragraph III.1. 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, if applicable, Warner Chilcott 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.
- 11. Warner Chilcott shall not seek payment for any of the 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.

- 12. Warner Chilcott 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 that payment of the Settlement Amount shall not render Warner Chilcott insolvent.
- 13. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 14. Warner Chilcott agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement relating to the Covered Conduct. Specifically, upon reasonable notice, Warner Chilcott 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 Warner Chilcott. Upon request, Warner Chilcott 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 any investigation of the Covered Conduct that is undertaken, or that has been performed by another on its behalf. Warner Chilcott shall be responsible for all costs it may incur in complying with this paragraph.
- 15. 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.

- 16. 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 person or entity.
- 17. 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.
- 18. In addition to all other payments and responsibilities under this Agreement, Warner Chilcott agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Warner Chilcott 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.
- 19. 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.
- 20. The undersigned Warner Chilcott 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.

- 21. 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.
- 22. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.
- 23. 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.
- 24. 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

Bý:	Raymond Liddy Deputy Attorney General California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse 1455 Frazee Road, Suite 315 San Diego, CA 92108 Ü	Ü	Dated: 9/36/15
y:	Original signed by Jennifer Kent Director Ü Department of Health Care Services MS 0000 P.O. Box 997413 Sacramento, CA 95899-7413 Ü		Dated: 1/30/15

Warner Chilcott Sales (U.S.) LLC

By:	Original Signed by	Dated: 10/29/15
	A. KOBERT D. BAILEY	
	President	
	Warner Chilcott Sales (U.S.) LLC	
By: _		Dated:
•	GEOFFREY E. HOBART	
	MATTHEW J. O'CONNOR	
	Covington & Burling LLP	
	Counsel for Warner Chilcott Sales (U.S.) LLC	

Warner Chilcott Sales (U.S.) LLC

By:	Dated:
A. ROBERT D. BAILEY μ	
President μ	
Warner Chilcott Sales (U.S.) LLC	
Original Signed By /	
By:	Dated:
GEÖFFREY E. HOBART	9
MATTHEW J. O'CONNOR	
Covington & Burling LLP	
Counsel for Warner Chilcott Sales (U.S.) L.J.C.	