

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Shire Pharmaceuticals LLC ("Shire"), hereinafter collectively referred to as "the Parties."

II. PREAMBLE

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

A. At all relevant times, Shire, a Delaware corporation with its principal place of business in Wayne, Pennsylvania, distributed, marketed, and sold drugs in the United States, including Adderall XR, Vyvanse, Daytrana, Lialda, and Pentasa (collectively the "Covered Drugs"). Adderall XR, Vyvanse, and Daytrana are approved by the U.S. Food and Drug Administration ("FDA") for the treatment of attention deficit hyperactivity disorder ("ADHD"). Lialda and Pentasa are FDA approved for the treatment of patients with mildly to moderately active ulcerative colitis.

B. On October 7, 2008, Relator Dr. Gerardo Torres filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States et al. ex rel. Torres v. Shire Specialty Pharmaceuticals et al.*, No. 08-4795 (E.D. Pa.), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3730(b) and various State False Claims Acts. On or about February 14, 2011, Relator Torres filed a Fifth Amended Complaint in the Eastern District of Pennsylvania under the same caption and case number (the "Pennsylvania Action"). On November 6, 2009, Relators Anita Hsieh, Ian Clark, and Kara Harris filed a *qui tam* action in the United States District Court for the Northern District of Illinois captioned *United States et al. ex Shire Settlement Agreement*, Case No. 09-08-01

rel. Hsieh et al. v. Shire PLC et al., No. 09-6994 (N.D. Ill.), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3730(b) and various State False Claims Acts (the “Illinois Action”). The Pennsylvania and Illinois Actions are hereinafter collectively referred to as the “Civil Actions.”

C. The Pennsylvania Action names the District of Columbia and the following 29 states: Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Utah, Virginia, and Wisconsin.

D. The Illinois Action names the District of Columbia and the following 22 states: California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

E. Shire will enter into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the United States (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the “United States.”

F. The State contends that Shire caused claims for payment to be submitted to the State’s Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).

G. The State contends that it has certain civil and administrative causes of action against Shire for engaging in the following conduct as to the Covered Drugs:

Adderall XR. From January 2004 through December 2007, Shire promoted Adderall XR as clinically superior to other ADHD drugs based on its

mechanism of action and its ability to “normalize” patients, despite a lack of clinical data sufficient to support such claims. Shire suggested to doctors that patients on Adderall XR would be moved “into a normalized condition with symptoms that are indistinguishable from [their] non-ADHD peers.” Shire also suggested that treatment with Adderall XR would help prevent several well-known negative consequences of ADHD, such as poor academic performance, loss of employment, criminal behavior, traffic accidents, and sexually transmitted disease. Over that same time period, Shire also promoted Adderall XR for the treatment of conduct disorder, an indication for use which was not approved by the FDA, was not a medically accepted indication (as defined by 42 U.S.C. § 1396r-8(k)(6)), and was not covered by the State’s Medicaid Program. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State’s Medicaid Program.

Vyvanse. From February 2007 through September 2010, Shire made promotional claims suggesting that treatment with Vyvanse would help prevent several well-known negative consequences of ADHD, despite a lack of clinical data sufficient to support such claims. For example, the company implied that use of Vyvanse would reduce the incidence of known consequences of ADHD such as car accidents, divorce, being arrested, and unemployment.

From February 2007 to September 2010, Shire marketed Vyvanse based on a claim that parents preferred Vyvanse to Adderall XR as a treatment for their children, despite a lack of clinical data sufficient to support such a claim.

Over the same time period, certain Shire sales representatives also promoted Vyvanse as “non-abuseable” and/or less abuseable than Adderall XR despite a lack of clinical data sufficient to support such a claim. In support of its claims about Vyvanse’s “abuseability,” certain Shire sales representatives relied on, and incorrectly characterized, studies referenced in the Vyvanse label that compared the drug liking effect (essentially the degree to which patients reported liking a drug) of Vyvanse and an equivalent dose of d-amphetamine (essentially, Adderall *immediate release* – a different drug from Adderall XR). The studies did not conclude that Vyvanse was not abuseable, nor did they offer any comparison of Vyvanse to Adderall XR.

In addition, from February 2007 through September 2010, certain Shire sales representatives and other agents made false and misleading statements about the efficacy and “abuseability” of Vyvanse to state Medicaid formulary committees in order to have the drug included on those states’ formularies and avoid the requirement of prior authorization for Medicaid prescriptions. For example, one Shire medical science liaison made false and misleading statements to a state formulary board that Vyvanse “provides less abuse liability” than “every other long-acting release mechanism” on the market.

Furthermore, from February 2007 through July 2008, certain Shire sales representatives knowingly and improperly made phone calls and drafted letters to Medicaid to assist physicians with the prior authorization process for Medicaid prescriptions of Vyvanse. Medicaid prior authorization programs are designed to ensure that only medically necessary services are provided in a cost-effective manner, and prior authorizations may only be requested by health care providers and their staff. When contacting Medicaid in connection with the prior authorization process, certain Shire

sales representatives failed to disclose that they worked for Shire. Shire sales representatives provided these prior authorization services to physicians to induce the physicians to prescribe Vyvanse paid for by the State's Medicaid Program. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Daytrana. From April 2006 to September 2010, Shire was aware that its Daytrana patches at times demonstrated difficulty in sticking to the patient's body and separating from the packaging. As a result, some patients either received less therapy than the patch was supposed to provide – *i.e.*, where the patch would fall off prematurely – or received no therapy from the patch because it could not be separated from the packaging. In addition, beginning in April 2006, certain Shire sales representatives marketed Daytrana as less abuseable than traditional, pill-based medications, despite a lack of clinical data sufficient to support such a claim.

Furthermore, from April 2006 through July 2008, certain Shire sales representatives knowingly and improperly made phone calls and drafted letters to Medicaid to assist physicians with the prior authorization process for Medicaid prescriptions of Daytrana. When contacting Medicaid in connection with the prior authorization process, certain Shire sales representatives failed to disclose that they worked for Shire. Shire sales representatives provided these prior authorization services to physicians to induce the physicians to prescribe Daytrana paid for by the State's Medicaid Program. The State further alleges that as a result of the behavior described

above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Lialda. From January 2007 through June 2010, certain Shire sales representatives promoted Lialda for the prevention of colorectal cancer, an indication for use which was not approved by the FDA; was not a medically accepted indication, as defined by 42 U.S.C. § 1396r-8(k)(6); and was not covered by the State's Medicaid Program. Certain sales representatives promoted Lialda by linking increased tissue concentration and a slower dissolution rate to increased efficacy, despite a lack of clinical data sufficient to support such claims. Shire also marketed Lialda based, in part, on claims that the medication had greater efficacy than other medications, specifically, that Lialda would induce "complete remission" of mild to moderate ulcerative colitis, despite a lack of clinical data sufficient to support such a claim. The State further alleges that as a result of the behavior described above, Shire knowingly caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Pentasa. From January 2006 through June 2010, certain Shire sales representatives promoted Pentasa for the treatment of indeterminate colitis, an indication for use which was not approved by FDA; was not a medically accepted indication, as defined by 42 U.S.C. § 1396r-8(k)(6); and was not covered by the State's Medicaid Program. Additionally, during the same time period, Shire promoted Pentasa for the treatment of Crohn's disease, an indication for use which was not approved by the FDA. The State further alleges that as a result of the behavior described above, Shire knowingly

caused false or fraudulent claims to be submitted for payment of the Covered Drugs by the State's Medicaid Program.

Shire's conduct as described immediately above in Section II.G. as to the Covered Drugs will hereinafter be referred to as the "Covered Conduct."

H. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Shire nor a concession by the State that its claims are not well founded. Shire expressly denies the allegations of the State and the Relators set forth herein and in the Civil Actions.

I. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above 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 set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Shire shall pay to the United States and the Medicaid Participating States (as defined in subparagraph (c) below), collectively, the sum of Fifty-Six Million Five Hundred Thousand Dollars (\$56,500,000.00), plus interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment under this agreement (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 the Federal Settlement Agreement, and

subject to the terms of this Agreement. The debt shall be forever discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Shire shall pay to the United States the sum of \$35,713,965.22, plus accrued interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment as set forth above (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Shire shall pay to the Medicaid Participating States the sum of \$20,786,034.78, plus interest at the rate of 1.375 percent per annum from February 1, 2013, and continuing until and including the date of payment (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of subparagraph (c) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 57 day opt-in period for Medicaid Participating States as described in subparagraph (c) below. 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 Shire.

(c) Shire shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Shire and the State Team have agreed, or in a form otherwise agreed to by Shire and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the

State and delivered to counsel for Shire within 57 days of receiving this Agreement. If this condition is not satisfied within 57 days, Shire's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Shire and the State Team to extend the 57 day period.

(d) The total portion of the amount paid by Shire in settlement for the Covered Conduct to the State is \$2,788,361.83, consisting of an amount paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$967,290.68, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 57 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Shire absent written agreement between counsel for Shire and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Shire in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Actions. Contingent upon the receipt of their respective State Amounts, the State, if served with the Civil Actions and liable to pay a Relator's share, agrees to pay the Relators the amount of \$181,836.03, plus applicable interest, agreement as to which shall be set forth in side letters issued to and executed by the Relators in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Shire set forth in this Agreement, and conditioned upon receipt by the State

of its share of the Medicaid State Settlement Amount, the State agrees to release Shire, together with its current and former parent corporations; current and former direct and indirect subsidiaries; current and former brother or sister corporations; current and former divisions; current and former owners; current and former affiliates; current and former directors, officers, and employees; and the predecessors, successors, transferees, and assigns of any of them (the "Shire Released Parties") from any civil or administrative monetary claim that the State has or may have for any claims submitted or caused to be submitted to the State Medicaid Program as a result of 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 of the Shire 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; and (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 based upon obligations created by this Agreement;
- (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(g) except with respect to Daytrana, any liability for express or implied warranty claims or other claims for defective or deficient products and services provided by Shire;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

(i) except with respect to Daytrana, any liability based on a failure to deliver goods or services due.

5. In consideration of the obligations of Shire set forth in this Agreement, and the Corporate Integrity Agreement (“CIA”) entered into between the Office of the Inspector General of the United States Department of Health and Human Services (“HHS-OIG”) and Shire North American Group, Inc. in connection with this matter, and conditioned on receipt by the State of its share of the State Medicaid Settlement Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State’s Medicaid Program against Shire plc, and Shire North American Group, Inc., and its operating subsidiaries for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against Shire in the event that Shire is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Shire waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment

of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, Shire waives and discharges the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Shire has asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Shire must pay to the State pursuant to Paragraph 1(d), above, will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid Program for the Covered Conduct. Shire further agrees not to resubmit to the State's Medicaid Program any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

9. Shire shall not seek payment for any claims for reimbursement to the State Medicaid Program covered by this Agreement and attributable in any way to the Covered Conduct, from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

10. Shire expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

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

12. Except as previously 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.

13. Except as otherwise stated in this Agreement, 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.

14. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for the purposes of the State's revenue code.

15. In addition to all other payments and responsibilities under this Agreement, Shire agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Shire 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.

16. Upon receipt of the payments described in Paragraph 1(d), above, the State, in connection with the Civil Actions, shall promptly sign and file a Stipulation of Dismissal of those Civil Actions pursuant to Rule 41(a)(1) as follows:

(a) the Stipulations of Dismissal shall be with prejudice to the State claims against Shire as to the Covered Conduct; and

(b) the Stipulations of Dismissal shall be without prejudice to the State as to all other claims.

17. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, 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.

18. The undersigned Shire signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

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

20. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF NORTH CAROLINA

By: Charles H. Hobergood

CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

Dated: 7/23/2014

By: Robin G. Cummings

ROBIN G. CUMMINGS, M.D., Director
Division of Medical Assistance

Dated: 7/17/14

SHIRE

DATED: 9/17/14 BY: Ellen Rosenberg
Ellen Rosenberg
Senior Vice President and Associate General Counsel

DATED: 9/17/14 BY: Melissa Bayer Tearney
R.J. Cinquegrana
Melissa Bayer Tearney
Counsel for Shire