

SETTLEMENT AGREEMENT

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 Defense Health Agency (“DHA”), acting on behalf of the TRICARE program, the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”), the United States Department of Veterans Affairs (“VA”), and the Department of Defense’s Defense Logistics Agency (“DLA”) (collectively the “United States”), Shire Pharmaceuticals LLC (“Shire”), and Gerardo Torres, M.D., Anita Hsieh, Ian Clark, and Kara Harris (collectively “Relators”) (hereinafter collectively with Shire, Relators, and the United States referred to as the “Parties”), through their authorized representatives.

RECITALS

A. Shire is a Delaware corporation with its principal place of business in Wayne, Pennsylvania. At all relevant times, Shire distributed, marketed, and sold drugs, 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 Torres filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Torres et al. v. Shire Specialty Pharmaceuticals et al.*, No. 08-4795 (E.D. Pa.),

pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). 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 Hsieh, Clark, and Harris filed a *qui tam* action in the United States District Court for the Northern District of Illinois captioned *United States ex rel. Hsieh et al. v. Shire PLC et al.*, No. 09-6994 (N.D. Ill.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Illinois Action”). The Pennsylvania and Illinois Actions are hereinafter collectively referred to as the Civil Actions.

C. The United States contends that it has certain civil claims against Shire, as specified in Paragraph 4 below, for engaging in the following conduct arising from Shire’s distribution, marketing, and sale of the Covered Drugs. The United States alleges the following:

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 certain issues linked to 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 state Medicaid programs.

Vyvanse. From February 2007 through September 2010, Shire made promotional claims suggesting that treatment with Vyvanse would help prevent certain issues linked to ADHD, despite a lack of clinical data sufficient to support such claims. For example, the company implied that use of Vyvanse would reduce 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 Shire’s 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 Medicaid.

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.*, when 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 Medicaid.

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 United States or state Medicaid programs. 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.

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 United States or state Medicaid programs. Additionally, during the same period, Shire promoted Pentasa for the treatment of Crohn’s disease, an indication for use which was not approved by the FDA.

Shire's alleged conduct as described in this Recitals Paragraph C will hereinafter be referred to as the "Covered Conduct."

D. The United States alleges that, as a result of the Covered Conduct, Shire knowingly caused false or fraudulent claims to be submitted for the payment of the Covered Drugs to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program ("TRICARE"), 10 U.S.C. §§ 1071-1110a; the FEHBP, 5 U.S.C. §§ 8901-8914; and the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396-1396w-5; and caused purchases of the Covered Drugs by the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743; and the Defense Logistics Agency (collectively the "Federal Programs"). The United States contends that engaging in the Covered Conduct and causing the submission of false or fraudulent claims to the Federal Programs gives rise to civil liability under the False Claims Act, 31 U.S.C. §§ 3729-3733, or common law.

E. Shire has entered into, or will enter into, separate settlement agreements, described in Paragraph 1 below, with certain states and the District of Columbia in settlement of the Covered Conduct (hereinafter referred to as the "Medicaid State Settlement Agreements"). States with which Shire executes a Medicaid State Settlement Agreement shall be referred to as "Medicaid Participating States."

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

G. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relators' reasonable expenses, attorneys' fees, and costs.

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. Shire shall pay to the United States and the Medicaid Participating States 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 (the "Settlement Amount").

Payments shall be made as follows:

(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 by electronic funds transfer no later than seven (7) business days after the Effective Date of this Agreement pursuant to written instructions from the Civil Division of the United States Department of Justice.

(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"). The Medicaid State Settlement Amount shall be paid by electronic

funds transfer no later than seven (7) business days after the Effective Date of this Agreement pursuant to written instructions from the National Association of Medicaid Fraud Control Units (“NAMFCU”) under the terms and conditions of the Medicaid State Settlement Agreements.

2. Conditioned upon the United States receiving the Settlement Amount from Shire and as soon as feasible after receipt, the United States shall pay \$5,900,000, plus a proportionate share of the actual accrued interest paid to the United States by Shire, to Relator Torres by electronic funds transfer.

3. Shire agrees to pay Relators and Relators’ counsel \$922,086 in full satisfaction of their claims for expenses, attorneys’ fees, and costs under 31 U.S.C. § 3730(d), no later than ten business days after the Effective Date of this Agreement, by electronic funds transfer pursuant to instructions provided by Relators’ counsel.

4. Subject to the exceptions in Paragraph 10 (concerning excluded claims) below, and conditioned upon Shire’s full payment of the Settlement Amount, the United States releases 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 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); or the common law theories for fraud, payment by mistake, disgorgement, unjust enrichment, and, if applicable, breach of contract.

5. Subject to the exceptions in Paragraph 10 below, and conditioned upon Shire's full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release the Shire Released Parties from any civil monetary claim they have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Conditioned upon Shire's full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents and assigns, agree to return to Shire, or to give to their respective counsel either to destroy or to retain in counsel's confidential files and not to disseminate, any hard copies of documents or communications in their possession or control that can be readily identified as having been created in whole or in part by, or at the direction of, Shire, or in connection with work done for Shire and to take reasonable steps to destroy any electronic copies of any such documents or communications. In the event that a third party requests any of the materials, Relators' counsel shall notify Shire of the request and shall not disclose or permit access to the materials without Shire's advance knowledge and written consent. The obligations of this Paragraph do not apply: (1) to documents or information in the public record or domain; (2) to the extent that compliance with the obligation would conflict with a statute or regulation; (3) if disclosure is required by a subpoena or

court order; or (4) to disclosure of non-privileged documents or information in conjunction with a government investigation.

7. In consideration of the obligations of Shire in this Agreement and the Corporate Integrity Agreement (“CIA”), entered into between the OIG-HHS and Shire North American Group, Inc., and conditioned upon Shire’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Shire plc, and Shire North American Group, Inc., and its operating subsidiaries under 42 U.S.C. § 1320a-7a (“Civil Monetary Penalties Law”) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 10 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Shire plc, and Shire North American Group, Inc., and its operating subsidiaries from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 10, below.

8. In consideration of the obligations of Shire set forth in this Agreement, and conditioned upon Shire’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 Shire plc, and Shire North

American Group, Inc., and its operating subsidiaries under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 10 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude Shire plc, and Shire North American Group, Inc., and its operating subsidiaries from the TRICARE Program 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 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 10 below.

9. In consideration of the obligations of Shire set forth in this Agreement, conditioned upon Shire's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against Shire plc, and Shire North American Group, Inc., and its operating subsidiaries under 5 U.S.C. § 8902a(c) or 5 C.F.R. Part 890, Subpart J, for the Covered Conduct, except as reserved in Paragraph 10 (concerning excluded claims), below and except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 10, below.

10. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, 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 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. Except with respect to Daytrana, any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- h. Except with respect to Daytrana, any liability for failure to deliver goods or services due.

11. Relators and their heirs, successors, attorneys, agents, and assigns shall not 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 expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the payment described in Paragraph 2 above, Relators and their 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 Actions or under 31 U.S.C. § 3730, and from any claim to a share of the proceeds of this Agreement and/or the Civil Actions.

12. Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, fully and finally release the Shire Released Parties from any civil monetary claims and any claims, allegations, demands, actions or causes of action whatsoever, 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 under common law that they have or may have against them, whether or not related to or arising from the United States' investigation and prosecution of the Civil Actions and the Covered Conduct, or from any past activities and actions of the Shire Released Parties, including without limitation, claims relating to or arising from the filing of the Civil Actions.

13. Shire waives and shall not assert any defenses Shire 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 of the Fifth Amendment to the United States Constitution, or under the Excessive Fines Clause of the Eighth Amendment to the United States 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.

14. The Shire Released Parties fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Shire Released Entities have asserted, could have asserted, or may assert in the future against

the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

15. In consideration of the obligations of the Relators set forth in this Agreement, the Shire Released Parties fully and finally release the Relators and their heirs, successors, attorneys, agents and assigns from any civil monetary claims and any claims, allegations, demands, actions or causes of action whatsoever, 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 under common law that the Shire Released Parties have against the Relators, whether or not related to or arising from the United States' investigation and prosecution of the Civil Actions and the Covered Conduct, or from any past activities and actions of the Relators.

16. 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 contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE or FEHBP carrier or payer, or any state payer (including any Medicaid contractor, fiscal intermediary, or carrier), related to the Covered Conduct; and Shire agrees not to resubmit to any Medicare contractor, 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.

17. Shire 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 Shire, its 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 investigation(s) of the matters covered by this Agreement;
- (3) Shire's investigation, defense, and 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;
- (5) the payment Shire makes to the United States pursuant to this Agreement and any payments that Shire may make to Relators, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
 - (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as

Unallowable Costs). However, nothing in Paragraph 17(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Shire.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Shire 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 Shire 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. Shire agrees that the United States, at a minimum, shall be entitled to recoup from Shire 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 Shire or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Shire 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 Shire's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

18. 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 19 (waiver for beneficiaries Paragraph), below.

19. Shire 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.

20. Upon receipt of the payments described in Paragraph 1, above, the United States and Relators, in their respective 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 United States' and Relators' claims against Shire as to the Covered Conduct; and

(b) the Stipulations of Dismissal shall be without prejudice to the United States and with prejudice to the Relators as to all other claims.

21. 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.

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

23. 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.

24. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

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

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 Shire's successors, transferees, heirs, and assigns.

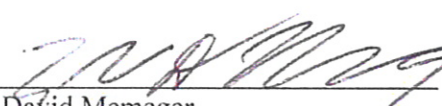
28. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

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

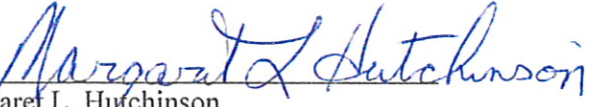
30. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

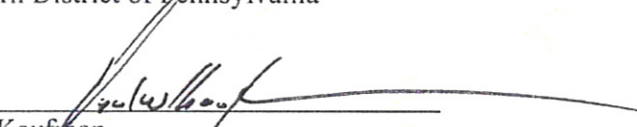
DATED: 9/19/2014

BY: 
Zane David Memeger
United States Attorney
Eastern District of Pennsylvania

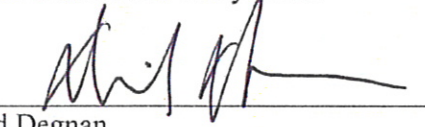
DATED: 9/19/2014

BY: 
Margaret L. Hutchinson
Assistant United States Attorney
Chief, Civil Division
Eastern District of Pennsylvania

DATED: 9/19/2014

BY: 
Paul Kaufman
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: 9/19/2014

BY: 
David Degnan
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____

BY: _____
Zachary T. Fardon
United States Attorney
Linda A. Wawzenski
Assistant United States Attorney
Northern District of Illinois

DATED: _____

BY: _____
Michael D. Granston
Jamie Ann Yavelberg
Natalie A. Priddy
Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
Zane David Memeger
United States Attorney
Eastern District of Pennsylvania

DATED: _____

BY: _____
Margaret L. Hutchinson
Assistant United States Attorney
Chief, Civil Division
Eastern District of Pennsylvania

DATED: _____

BY: _____
Paul Kaufman
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____

BY: _____
David Degnan
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: 9/19/2014

BY: Linda A. Wawzenski
Zachary T. Fardon
United States Attorney
Linda A. Wawzenski
Assistant United States Attorney
Northern District of Illinois

DATED: 9/19/2014

BY: Natalie Priddy
Michael D. Granston
Jamie Ann Yavelberg
Natalie A. Priddy
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/12/14

BY: Robert K. DeConti

Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: _____

BY: _____

Paul J. Hutter
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____

Alan P. Spielman
Assistant Director of Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED: _____

BY: _____

J. David Cope
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED: _____

BY: _____

Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: 2 Sep 2014

BY: B. J. Hutter, Deputy Gen. Counsel
for Paul J. Hutter
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____

Alan P. Spielman
Assistant Director of Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED: _____

BY: _____

J. David Cope
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED: _____

BY: _____

Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: _____

BY: _____

Paul J. Hutter
General Counsel
Defense Health Agency
United States Department of Defense

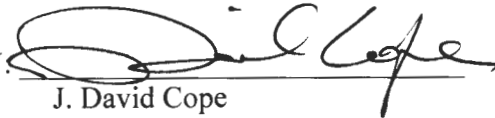
DATED: _____

BY: _____

Alan P. Spielman
Assistant Director of Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED: 8/28/2014

BY: _____



J. David Cope
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED: _____

BY: _____

Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: _____

BY: _____

Paul J. Hutter
General Counsel
Defense Health Agency
United States Department of Defense

DATED: 8/28/14

BY: *Alan P. Spielman*

Alan P. Spielman
Assistant Director of Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED: _____

BY: _____

J. David Cope
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management


SHIRE

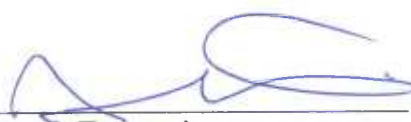
DATED: 9/17/14 BY: Ellen Rosenberg
Ellen Rosenberg
Senior Vice President and Associate General Counsel
Shire Pharmaceuticals LLC

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

RELATORS

DATED: 8/28/14 BY: 
Gerardo Torres, M.D.

DATED: 8/28/14 BY: 
Stephen A. Sheller
Counsel for Dr. Torres

DATED: 8/28/14 BY: 
Joseph Trautwein
Counsel for Dr. Torres

DATED: _____ BY: _____
Anita Hsieh

DATED: _____ BY: _____
Ian Clark

DATED: _____ BY: _____
Kara Harris


DATED: _____ BY: _____
David Chizewer
Matthew Organ
Colin Wexler
Counsel for Ms. Hsieh, Ms. Harris, and Mr. Clark

RELATORS

DATED: _____ BY: _____
Gerardo Torres, M.D.

DATED: _____ BY: _____
Stephen A. Sheller
Counsel for Dr. Torres

DATED: _____ BY: _____
Joseph Trautwein
Counsel for Dr. Torres

DATED: 9/2/14 BY: 
Anita Hsieh

DATED: _____ BY: _____
Ian Clark

DATED: _____ BY: _____
Kara Harris

DATED: _____ BY: _____
David Chizewer
Matthew Organ
Colin Wexler
Counsel for Ms. Hsieh, Ms. Harris, and Mr. Clark

RELATORS

DATED: _____ BY: _____
Gerardo Torres, M.D.

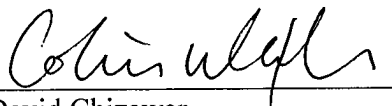
DATED: _____ BY: _____
Stephen A. Sheller
Counsel for Dr. Torres

DATED: _____ BY: _____
Joseph Trautwein
Counsel for Dr. Torres

DATED: _____ BY: _____
Anita Hsieh

DATED: _____ BY: _____
Ian Clark

DATED: _____ BY: _____
Kara Harris

DATED: _____ BY: 
David Chizewer
Matthew Organ
Colin Wexler
Counsel for Ms. Hsieh, Ms. Harris, and Mr. Clark

RELATORS

DATED: _____ BY: _____
Gerardo Torres, M.D.

DATED: _____ BY: _____
Stephen A. Sheller
Counsel for Dr. Torres

DATED: _____ BY: _____
Joseph Trautwein
Counsel for Dr. Torres

DATED: _____ BY: _____
Anita Hsieh

DATED: _____ BY: _____
Ian Clark

DATED: 8/27/14 BY: *Kara Harris*
Kara Harris

DATED: _____ BY: _____
David Chizewer
Matthew Organ
Colin Wexler
Counsel for Ms. Hsieh, Ms. Harris, and Mr. Clark

RELATORS

DATED: _____ BY: _____
Gerardo Torres, M.D.

DATED: _____ BY: _____
Stephen A. Sheller
Counsel for Dr. Torres

DATED: _____ BY: _____
Joseph Trautwein
Counsel for Dr. Torres

DATED: _____ BY: _____
Anita Hsieh

DATED: 8/28/2014 BY: *Ian Clark*
Ian Clark

DATED: _____ BY: _____
Kara Harris

DATED: _____ BY: _____
David Chizewer
Matthew Organ
Colin Wexler
Counsel for Ms. Hsieh, Ms. Harris, and Mr. Clark