# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. STEVEN R.PEIKIN, M.D., et al.,

Plaintiffs,

٧.

SALIX PHARMACEUTICALS, INC.,

Defendant.

UNITED STATES OF AMERICA et al. ex rel. RASVINDER DHALIWAL,

Plaintiffs,

v.

SALIX PHARMACEUTICALS, LTD.,

Defendant.

UNITED STATES OF AMERICA,

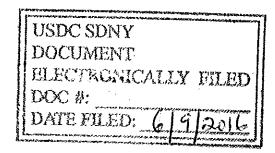
Plaintiff-Intervenor,

٧.

SALIX PHARMACEUTICALS, INC.,

Defendant.

12 Civ. 3870 (DLC)



15 Civ. 706 (DLC)

12 Civ. 3870 (DLC)

15 Civ. 706 (DLC)

### STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal ("Stipulation") is entered into by and among plaintiff the United States of America ("United States" or "Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District

of New York; the *qui tam* relators in *United States* ex rel. *Stephen R. Peikin, M.D.*, et al. v. *Salix Pharmaceuticals, Inc.*, 12 Civ. 3870 (DLC) ("Salix I Relators"), by their authorized representatives; the *qui tam* relator in *United States* et al. ex rel. *Rasvinder Dhaliwal v. Salix Pharmaceuticals, Ltd.*, 15 Civ. 706 (DLC) ("Salix II Relator" and together with the Salix I Relators, "Salix Relators"), by her authorized representatives; and defendant Salix Pharmaceuticals, Inc. a/k/a Salix Pharmaceuticals, Ltd. ("Salix" and together with the Government and the Salix Relators, "Parties"), by its authorized representatives;

WHEREAS, the Government alleges that from January 2009 through December 2013 ("Covered Period"), Salix knowingly offered and paid remuneration, including honoraria payments and meals, to physicians and other health care professionals who spoke at or attended speaker programs to induce them to recommend, promote, and prescribe certain Salix drugs and medical devices — specifically, Xifaxan, Apriso, Relistor, MoviPrep, OsmoPrep, Solesta, and Deflux ("Covered Products") — in violation of the Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. As a result of the foregoing conduct, the Government alleges that Salix knowingly submitted or caused to be submitted false claims for the Covered Products to, or caused purchases of the Covered Products by, Medicaid, Medicare, TRICARE, and the Department of Veteran Affairs, in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq. The conduct described in this paragraph is the "Covered Conduct" for purposes of this Stipulation;

WHEREAS, on or about May 15, 2012, the Salix I Relators filed a *qui tam* complaint against Salix in the United States District Court for the Southern District of New York (the "Court"), alleging, *inter alia*, that Salix had violated the AKS and FCA by engaging in the Covered Conduct with respect to certain of the Covered Products (specifically, Xifaxan, Apriso,

and Relistor). The Salix I Relators filed an amended complaint on or about October 18, 2012 ("Salix I Amended Complaint");

WHEREAS, on or about January 30, 2015, the Salix II Relator filed a *qui tam* complaint against Salix ("Salix II Complaint") in this Court, alleging, *inter alia*, that Salix had violated the AKS and FCA by engaging in the Covered Conduct with respect to all of the Covered Products;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government, through the Office of the United States Attorney for the Southern District of New York, is filing a Notice of Election to Partially Intervene and Complaint-In-Intervention in the above-referenced qui tam actions ("Government Complaint"), in which it is asserting claims against Salix arising under the AKS and FCA based on the Covered Conduct;

WHEREAS, Salix intends on entering into separate settlement agreements ("State Settlements") with various states that participate in the Medicaid Program ("States") to resolve claims related to the Covered Conduct and has agreed to pay a total of \$7,470,046.80 to the States pursuant to the State Settlements; and

WHEREAS, the Parties have, through this Stipulation, reached a mutually-agreeable resolution addressing the claims asserted against Salix in the Government Complaint, the Salix I Amended Complaint and the Salix II Complaint, arising out of the Covered Conduct;

NOW, THEREFORE, upon the Parties' agreement, IT IS HEREBY ORDERED that:

### TERMS AND CONDITIONS

- 1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.
  - 2. Salix admits, acknowledges, and accepts responsibility for the following conduct:
    - a. During the period January 2009 through December 2013 (the "Covered Period"), Salix conducted approximately 10,000 speaker programs for the

Covered Products. Approximately 8,000 of those speaker programs were for Xifaxan, Apriso and Relistor. Salix's speaker programs on the Covered Products included in-person events and pre-recorded events.

- (1) At in-person programs, both the speaker and the attendees were present in person, and the speaker was supposed to provide an educational talk on a Covered Product to the attendees, using a slide presentation created and approved by Salix.
- (2) At pre-recorded programs, the designated speaker did not appear in person. Instead, a Salix employee was supposed to use a laptop or other device to play for the attendees a pre-recorded video of a doctor delivering the slide presentation that was created and approved by Salix. At the end of the pre-recorded presentation, the Salix employee was supposed to call the designated speaker, who was to be available to answer any questions by telephone. Some Salix employees internally referred to these programs as "doc-in-the-box programs."
- b. For each speaker program, a physician (the "speaker") was paid an honorarium ranging from \$250 (for a doctor available on call to answer questions associated with a pre-recorded program) to \$4,500 (for a doctor who spoke at an in-person program and had a specified level of experience and certain credentials) per program to educate other healthcare professionals (the "attendees") on one of the Covered Products. During the Covered Period, Salix paid over 500 physicians honoraria in connection with its speaker programs on the Covered Products, with dozens of physicians earning more than \$50,000, and several earning more than \$100,000.
- c. Throughout the Covered Period, speaker programs were an important part of Salix's strategy for increasing the sales of the Covered Products. Members of the Salix sales force were encouraged to recruit new speakers and to schedule speaker programs, and some supervisors set goals for the number of programs sales representatives were expected to hold during a given period. Salix periodically monitored the prescription writing data of the physicians who attended speaker programs, and selected for future invites those doctors who prescribed comparatively more of Salix's drugs or who Salix identified as having the potential to be high prescribers.
- d. Salix's speaker programs were typically held in restaurants, and a meal was provided to the speaker and attendees. Pursuant to Salix's internal policies, the venue for these programs was supposed to be "conducive" to the exchange of information. In addition, the cost of the meal was supposed to be "modest" by local standards of restaurant meals, and the attendees were supposed to consist entirely of healthcare professionals

with a legitimate interest in the scheduled topic. Speaker programs were supposed to involve the presentation of scientific or clinical information about the relevant Salix product.

- e. Throughout the Covered Period, numerous Salix employees held speaker programs for the Covered Products that were primarily social in nature and/or otherwise did not comply with Salix's internal policies. For example, there were programs where:
  - the designated speaker spent little or no time discussing the Covered Product;
  - the required slide presentation was not shown at all or in its entirety;
  - doctors attended multiple programs on the same topic (at which the same slide presentation was supposed to have been shown) within a short period of time;
  - the programs were held in the main dining rooms of restaurants or other locations that were not conducive to an educational program;
  - the programs were held at high-end restaurants (such as Nobu and Le Bernardin in New York City), with per-person costs exceeding \$200 and even \$300;
  - the Salix sales representative responsible for a program reported that certain physicians had attended the event even though they had not, in order to make the per-person cost of the event appear lower than it actually was;
  - attendees included individuals other than healthcare professionals with a legitimate interest in the scheduled topic, such as a physician's spouse; and/or
  - the programs were used as an opportunity to provide a physician's practice (in some cases including administrative staff) with a meal or a happy hour.
- f. Additionally, with respect to the pre-recorded speaker programs, there were numerous instances where: (1) the Salix sales representative did not play the pre-recorded presentation; (2) the Salix sales representative played the pre-recorded presentation but placed the laptop or other viewing device in a location where it could not readily be seen or at a volume at which it could not readily be heard; and/or (3) the designated

- approved speaker was not called at the end of the pre-recorded presentation but still received an honoraria payment.
- g. Throughout the Covered Period, Salix did not have effective mechanisms to monitor adequately its speaker programs to ensure compliance with internal policies. For example:
  - there were no effective mechanisms in place to audit speaker programs and insufficient efforts were made to review data and other information on speaker programs to ensure compliance with internal policies;
  - sign-in sheets were not mandatory for much of the Covered Period, and even when they were mandatory, they were not consistently completed;
  - limited, if any, effort was made to proactively assess how often doctors presented the same program to the same attendees; and
  - there were instances where the per-person spending limits that Salix internally set for speaker programs were significantly exceeded.
- 3. Salix shall pay the Government \$46,529,953.20 within fourteen (14) business days of the Effective Date (defined below in Paragraph 30), plus interest, which shall be compounded annually at a rate of 1.75% accruing from March 29, 2016, to the date of payment ("Settlement Amount").
- 4. The payment required by Paragraph 3 above shall be made in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York.
- 5. Salix agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Salix 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. Salix further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, 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 another on its behalf, as well as complete and unredacted copies of any other non-privileged documents in its possession, custody, or control relating to the Covered Conduct.

- 6. Subject to the exceptions in Paragraph 11 below (concerning excluded claims) and Paragraph 18 below (concerning bankruptcy proceedings), and conditioned on Salix's full payment of the Settlement Amount as set forth in Paragraph 3 above, the United States releases Salix, together with its current and former direct and indirect parent corporations ("Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their corporate predecessors, successors, transferees, and assigns of any of them, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake and unjust enrichment.
- 7. Conditioned on Salix making the required payment set forth in Paragraph 3 above and the payment Salix is required to make under the State Settlements, and subject to Paragraph 18 below (concerning bankruptcy proceedings), the Salix I Relators, for themselves and their heirs, successors, attorneys, agents, and assigns, release Salix, together with its current and former Parents; its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; its and their corporate predecessors, successors, transferees, and assigns of any of them; and its and their respective current and former owners, officers, directors,

employees, and agents, individually or collectively (collectively, the "Salix Releasees") from:

(a) any civil monetary claims that the Salix I Relators have or may have on behalf of the United States for the Covered Conduct under the FCA, and (b) any and all 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, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that the Salix I Relators, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including but not limited to, any liability to the Salix I Relators arising from or relating to the claims that the Salix I Relators asserted or could have asserted in the Salix I Amended Complaint or the Salix II Complaint.

8. Conditioned on Salix making the required payment set forth in Paragraph 3 above and the payment Salix is required to make under the State Settlements, and subject to Paragraph 18 below (concerning bankruptcy proceedings), the Salix II Relator, for herself and her heirs, successors, attorneys, agents, and assigns, releases the Salix Releasees from: (a) any civil monetary claims that the Salix II Relator has or may have on behalf of the United States for the Covered Conduct under the FCA, and (b) any and all claims that the Salix II Relator has asserted or could have asserted for any act, event, or conduct arising from or relating to the allegations in the Salix I Amended Complaint or the Salix II Complaint, provided, however, that nothing in this Stipulation shall release Salix from any claims of the Salix II Relator for, or preclude the Salix II Relator from seeking to recover, her reasonable expenses, costs, and attorneys' fees from Salix pursuant to 31 U.S.C. § 3730(d), and, further, nothing in this Stipulation shall release Salix from, or preclude the Salix II Relator for retaliation

arising under 31 U.S.C. § 3730(h), the New York False Claims Act, N.Y. Fin. Law §191 and/or 15 U.S.C. § 78u-6(h), including any related claims for litigation costs and reasonable attorneys' fees arising under such statutes, and/or claims of breach of any contract between Salix and the Salix II Relator related to the employment relationship between Salix and the Salix II Relator, including as alleged in the Salix II Complaint (collectively, the "Surviving Claims"). Moreover, nothing in this Stipulation shall release, extinguish or broaden any existing statutory or contractual rights that Salix II Relator has against Salix, if any, for indemnification and the advancement of attorneys' fees, in actions or investigations subject to the exercise of such statutory or contractual rights.

- 9. In consideration of the execution of this Stipulation by the Salix I Relators, and the releases by the Salix I Relators as set forth in Paragraph 7 above, the Salix Releasees release the Salix I Relators, and their heirs, successors, attorneys, agents, and assigns, individually and collectively, from any and all claims that Salix has asserted or could have asserted for any act, event, or conduct relating to the allegations in the Salix I Amended Complaint or the Government Complaint, in addition to any claims previously released related to the separation of any of the Salix I Relators' employment with Salix and/or Valeant Pharmaceuticals International, Inc.
- 10. In consideration of the execution of this Stipulation by the Salix II Relator, and the release by the Salix II Relator as set forth in Paragraph 8 above, the Salix Releasees release the Salix II Relator, and her heirs, successors, attorneys, agents, and assigns, individually and collectively, from any and all claims that Salix has asserted or could have asserted for any act, event, or conduct arising from or relating to the allegations in the Salix II Complaint or the Government Complaint, provided, however, that Salix reserves and does not release its right to

assert any defenses or claims as to the Salix II Relator's or Salix II Relator's counsels' claims for reasonable expenses, costs or attorneys' fees reserved pursuant to 31 U.S.C. § 3730(d) or the Salix II Relator's Surviving Claims.

- 11. Notwithstanding the releases given in Paragraph 6 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:
- a. any liability arising under Title 26, United States Code (Internal Revenue Code);
  - b. any criminal liability;
- c. except as explicitly stated in this Stipulation, any civil or administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. any liability to the Government (or its agencies) for any conduct other than the Covered Conduct;
  - e. any liability based upon obligations created by this Stipulation; and
  - f. any liability of individuals.
- 12. Salix shall be in default of this Stipulation if Salix fails to make the required payment set forth in Paragraph 3 above, or if it fails to comply materially with any other term of this Stipulation that applies to it ("Default"). The Government shall provide written notice of any Default in the manner set forth in Paragraph 29 below. Salix shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Settlement Amount,

beginning seven (7) business days after mailing of the notice of Default. In the event of an Uncured Default, Salix agrees to the entry of the consent judgment attached hereto as Exhibit A and that the Government may take action to collect on the consent judgment. In the event of an Uncured Default, Salix further agrees that the United States, at its option, may (a) rescind this Stipulation and, following repayment to Salix of the Settlement Amount and interest (less reasonable costs of collection and enforcement described below in this paragraph), reinstate the Government Complaint, as well as any claims that could be asserted for the Covered Conduct (in the event the Government Complaint is reinstated, the Salix Relators could also reinstate their Complaints); (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount (including interest) from any amounts due and owing Salix at the time of default by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Salix shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Salix shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Salix shall 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 that relate to the Covered Conduct.

13. The Salix Relators, and their heirs, successors, attorneys, agents, and assigns, shall not object to this Stipulation but agree and confirm that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Stipulation and the above-referenced civil actions, the Salix Relators, and

their heirs, successors, attorneys, agents, and assigns agree that neither this Stipulation, any intervention by the United States in the above-referenced civil actions in order to dismiss the civil actions, nor any dismissal of the civil actions, shall waive or otherwise affect the ability of the United States to contend that any provision in the FCA, including 31 U.S.C. §§ 3730(b)(5), bar the Salix Relators from sharing in the proceeds of this Stipulation. Moreover, the United States and the Salix Relators, and their heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the FCA on the issue of the share percentage, if any, that the Salix Relators should receive of any proceeds of the settlement of their claims. Subject to any claims that the Salix Relators may have under 31 U.S.C. § 3730(d) for their share of the Settlement Amount, the Salix Relators, for themselves, and for their respective heirs, successors, attorneys, agents, and assigns, release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims, known or unknown, arising from the filing of the Salix I Amended Complaint and the Salix II Complaint and from any claims under 31 U.S.C. § 3730.

14. Salix waives and shall not assert any defenses Salix 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action.

Nothing in this Paragraph or any other provision of this Stipulation 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.

- 15. Salix fully and finally releases 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 Salix has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, or servants, related to the Covered Conduct, the United States' investigation, prosecution and settlement of the Covered Conduct, and the United States' investigation (as of the Effective Date) of the claims asserted in the Salix I Amended Complaint and the Salix II Complaint.
- 16. This Stipulation 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 as otherwise provided herein.
- 17. Salix represents and warrants that it has reviewed its financial situation, 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 it reasonably believes as of the date hereof that it shall remain solvent following compliance with its obligations under this Stipulation. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Salix within the meaning of 11 U.S.C. § 547(e)(1); and (b) have concluded that these mutual promises, covenants, and obligations due, 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 Salix was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).
- 18. If Salix commences, or a third party commences, any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors

- (a) seeking an order for relief of Salix's debts, or seeking to adjudicate Salix as bankrupt or insolvent; or (b) seeking appointment of a trustee, custodian, or other similar official for Salix or for all or any substantial part of Salix's assets, Salix agrees as follows:
- a. Salix's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Salix shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Salix's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Salix was insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Salix.
- b. If Salix's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its sole option, may rescind the releases in this Agreement and reinstate the Government Complaint or bring any civil and/or administrative claim, action, or proceeding against Salix that would otherwise be covered by the release in Paragraph 6 above. Salix agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first clause of this Paragraph, and Salix shall not argue or otherwise contend that the claim, action, or proceeding is subject to an automatic stay; (ii) Salix shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government or the Salix Relators within 60 calendar days of written notification that the releases in the Stipulation have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the date the Salix I Amended Complaint and/or Salix II Complaint

were originally filed; and (iii) the Government has a valid claim against Salix for the full Settlement Amount, and the Government may pursue the claim in the case, action, or proceeding described in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

- c. Salix acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.
  - 19. Salix 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 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Salix, including its present or former officers, directors, employees, shareholders and agents, in connection with:
  - (1) the matters covered by this Stipulation;
  - (2) the United States' audit(s) and civil and/or criminal investigation(s) of matters covered by this Stipulation;
  - (3) Salix's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and/or criminal investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
    - (4) the negotiation and performance of this Stipulation; and
  - (5) any payments Salix makes to the United States pursuant to this Stipulation and any payments Salix may make to the Salix Relators, including expenses, costs and attorneys' fees,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Salix, and Salix 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 Salix or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: Salix further agrees that within 90 days of the Effective Date of this Stipulation, 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 Salix 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. Salix agrees that the United States, at a minimum, shall be entitled to recoup from Salix 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 Salix or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Salix or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Salix's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 20. Upon receipt of the payment described in Paragraph 3 above and the payment Salix is required to make under the State Settlements, the United States and the Salix Relators shall file pursuant to Rule 41(a)(1) a Notice of Dismissal of the Government Complaint, the Salix I Amended Complaint, and the Salix II Complaint. As to the United States, the dismissal shall be with prejudice only as to claims related to the Covered Conduct that are being released pursuant to this Stipulation, and shall be without prejudice as to all other claims and conduct. As to the Salix I Relators, the dismissal shall be with prejudice as to all claims in the Salix I Amended Complaint. As to the Salix II Relator, the dismissal shall be with prejudice as to all claims in the Salix II Complaint, provided, however, that the following claims shall not be dismissed, unless they are settled, adjudicated, or otherwise resolved: (a) the Salix II Relators' claims for reasonable expenses, costs, or attorneys' fees reserved pursuant to 31 U.S.C.

- § 3730(d); and (b) the Salix II Relator's Surviving Claims. However, the Court shall retain jurisdiction over this Stipulation to enforce Salix's obligations pursuant to Paragraph 5 above.
- 21. Except as set forth in Paragraphs 8 and 20 above (which preserve the Salix II Relator's rights against Salix to seek reasonable expenses, costs, and attorneys' fees, as well as the rights to pursue any claim preserved in Paragraphs 8 and 20 above), each Party shall bear its own legal and other costs incurred in connection with this matter.
- 22. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.
- 23. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party in any subsequent dispute.
- 24. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties.
- 25. The undersigned counsel and any other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of persons and the entities indicated below.
  - 26. This Stipulation is binding on Salix and any successor entities.

- 27. This Stipulation is binding on the Salix Relators' successors, transferees, heirs, and assigns.
- 28. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.
- 29. Any notices or requests pursuant to this Stipulation shall be in writing and shall be delivered by hand, express courier, or email transmission followed by postage-prepaid mail, and shall be addressed as follows:

### IF TO THE UNITED STATES:

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### IF TO SALIX:

Nancy L. Kestenbaum Covington & Burling LLP The New York Times Building 620 Eighth Avenue New York, New York 10018 Email: nkestenbaum@cov.com

Matthew J. O'Connor Patrick M. Phelan Covington & Burling LLP One CityCenter 850 Tenth Street, NW Washington, D.C. 20001 Email: moconnor@cov.com

### pphelan@cov.com

30. The Effective Date of this Stipulation is the date upon which the Stipulation is approved and entered by the Court.

Agreed to by:

### THE UNITED STATES OF AMERICA

Dated: New York, New York June 2, 2016

> PREET BHARARA United States Attorney for the Southern District of New York

By:

JEFFREY K. POWELL CHRISTOPHER B. HARWOOD Assistant United States Attorneys 86 Chambers Street, Third Floor New York, New York 10007 Telephone: (212) 637-2706/2728

effer forell

Facsimile: (212) 637-2786

Attorney for the United States of America

So endered. June 9, 2012

# SALIX I RELATORS

Dated: June 2, 2016

Relator

Dated: June 2, 2016

SEANA SWIERCZEK

Relator

Dated: June 2, 2016

By:

CHRISTINE MOORE

Relator

Dated: June 2, 2016

By:

PAUL MASTRELLA Relator

Dated: June 2, 2016

McELDREW YOUNG

By:

YAMES J. MCELINEW IILESO

123 S. Broad Street, Suite 2258

Philadelphia, PA 19109 Telephone: (215) 545-8800 Facsimile: (215) 367-5143

Attorneys for Salix I Relators

Dated: June 2, 2016

JOSEPH TRAUTWEIN & ASSOCIATES,

LLC

By:

JOSPEH TRAUTWEIN, ESQ. 1777 Septry Parkway West Veva Building 11, Suite 100 Blue Bell, PA 19422-2210 Telephone: (267) 464-1540

Facsimile: (267) 464-0400

Attorneys for Salix I Relators

## SALIX II RELATOR

Dated:

June 2, 2016

By:

RASVINDER DHALIWAL

Relator

Dated:

JUNE Z, 2016

GALLAGHER LAW OFFICES PLLC

By:

JOHN C. GALLAGHER III, ESQ. 178 Huguenot Street, Suite 200 New Rochelle, NY 10801

Telephone: (914) 618-5475 Facsimile: (888) 837-8142

Attorneys for Salix II Relator

## SALIX

| Dated: June 2, 2016                               |     |  |
|---|-----|--|
| ·   | Ву: | COVINGTON & BURLING LLP  |
|   | ۵,  | NANCY L. KESTENBAUM, ESQ.<br>The New York Times Building<br>620 Eighth Avenue  |
|   |     | New York, New York 10018 Email: nkestenbaum@cov.com  |
|   |     | MATHEW J. O'CONNOR, ESQ. PATRICK M. PHELAN, ESQ. One CityCenter 850 Tenth Street, NW Washington, D.C. 20001 Email: <a href="moconnor@cov.com">moconnor@cov.com</a> pphelan@cov.com |
|   |     | Attorneys for Salix  |
| Dated: June 2, 2016                               | Ву: | LINDA A. LAGORGA   |
|   |     | Senior Vice President and Treasurer Salix Pharmaceuticals, Inc.  |
| SO ORDERED:                                       |     |  |
| HON. DENISE L. COTE<br>UNITED STATES DISTRICT JUD | )GE | <del></del>  |
| Dated:, 2016                                      |     |  |

# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. STEVEN R. PEIKIN, M.D., et al.,

Plaintiffs,

٧,

12 Civ. 3870 (DLC)

SALIX PHARMACEUTICALS, INC.,

Defendant.

**CONSENT JUDGMENT** 

UNITED STATES OF AMERICA et al. ex rel. RASVINDER DHALIWAL,

Plaintiffs,

٧.

15 Civ. 706 (DLC)

SALIX PHARMACEUTICALS, LTD.,

Defendant.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

12 Civ. 3870 (DLC)

٧.

SALIX PHARMACEUTICALS, INC.,

15 Civ. 706 (DLC)

Defendant.

Upon the consent of plaintiff the United States of America and defendant Salix Pharmaceuticals, Inc. a/k/a Salix Pharmaceuticals, Ltd. ("Salix") it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of \$46,529,953.20 as against Salix, as well as post-judgment interest at the rate of 12% per annum compounded daily.

Agreed to by:

### THE UNITED STATES OF AMERICA

| Dated: | New York, New York |
|--------|--------------------|
|        | , 2016             |

PREET BHARARA
United States Attorney for the
Southern District of New York

By: \_\_\_\_\_

JEFFREY K. POWELL CHRISTOPHER B. HARWOOD Assistant United States Attorneys 86 Chambers Street, Third Floor New York, New York 10007 Telephone: (212) 637-2706 /2728 Facsimile: (212) 637-2786

Attorney for the United States of America

## **SALIX**

| Dated:                    | , 2016                        | ő   |  |
|---------------------------|-------------------------------|-----|--|
|                           |                               |     | COVINGTON & BURLING LLP  |
|                           |                               | Ву: |  |
|                           |                               | ,.  | NANCY L. KESTENBAUM, ESQ. The New York Times Building 620 Eighth Avenue New York, New York 10018 Email: <a href="mailto:nkestenbaum@cov.com">nkestenbaum@cov.com</a> |
|                           |                               |     | MATHEW J. O'CONNOR, ESQ. PATRICK M. PHELAN, ESQ. One CityCenter 850 Tenth Street, NW Washington, D.C. 20001 Email: moconnor@cov.com pphelan@cov.com                  |
|                           |                               |     | Attorneys for Salix  |
| Dated:                    | , 2016                        |     |  |
|                           |                               | Ву: | LINDA A. LAGORGA Senior Vice President and Treasurer Salix Pharmaceuticals, Inc.   |
| SO ORDEREI                | D:                            |     |  |
| HON. DENISI<br>UNITED STA | E L. COTE<br>TES DISTRICT JUD | GE  | <u></u>  |
| Dated:                    | , 2016                        |     |  |