Case 1:11-cv-08196-CM Document 41  UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	Filed 01/08/14 Page 1 of 22  DOCUM  BLECTIM  DOC 1: DAT   \$   4
UNITED STATES OF AMERICA,	x : 11 Civ. 8196 (CM)
Plaintiff-Intervenor, v.	STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL
NOVARTIS PHARMACEUTICALS CORP., and BIOSCRIP, INC.,	: As to BioScrip, Inc.
Defendants.	: :

WHEREAS, this Stipulation and Order of Settlement and Dismissal (the "Stipulation") is entered into by and among plaintiff the United States of America (the "United States"), by its attorney Preet Bharara, United States Attorney for the Southern District of New York, and defendant BioScrip, Inc. ("BioScrip"), through their respective authorized representatives;

WHEREAS, in November 2011, David Kester ("Relator," and, together with the United States and BioScrip, the "Settling Parties") filed a sealed *qui tam* action (the "Action") in the United States District Court for the Southern District of New York (the "Court") pursuant to 31 U.S.C. § 3730(b), the *qui tam* provision of the False Claims Act, 31 U.S.C. § 3729 et seq. (the "FCA"), alleging, *inter alia*, that defendants Novartis Pharmaceuticals Corp. ("Novartis") and BioScrip violated the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), in connection with distributing the iron chelation drug Exjade;

WHEREAS, in October 2012, and in connection with its investigation of the Relator's allegations, the United States served a civil investigative demand on BioScrip;

WHEREAS, on September 11, 2013, the United States first notified BioScrip that the United States was contemplating civil claims against BioScrip under the FCA relating to BioScrip's distribution of Exjade (but did not at that time reveal the existence of the Action

under seal or the fact that BioScrip was named as a defendant therein by the Relator);

WHEREAS, commencing in late September 2013, the United States and BioScrip have pursued extensive discussions concerning the claims against BioScrip that the United States was contemplating;

WHEREAS, in connection with its discussions with the United States, BioScrip has submitted records and information regarding its financial circumstances, and has demonstrated to the United States that BioScrip lacks the financial wherewithal to pay certain damages and penalties sought by the United States in connection with its claims against BioScrip;

WHEREAS, on October 30, 2013, the United States further intervened in the Action against Novartis based on Novartis's alleged participation in a kickback scheme with BioScrip;

WHEREAS, on January 6, 2014, the United States intervened against BioScrip and submitted an Amended Complaint-in-Intervention;

WHEREAS, the United States's Amended Complaint alleges – as relevant to this settlement – that from February 2007 to May 2012, Novartis and BioScrip engaged in a kickback scheme in connection with the distribution of Exjade (as set forth in paragraphs 1–44, 142–232, and 252–273 of the Amended Complaint, the "Covered Conduct"), resulting in violations of the FCA and the AKS and the payments of Exjade claims by Medicare and Medicaid that should not have been reimbursed by those federal healthcare programs;

WHEREAS, to avoid the delay, uncertainty, and expense of protracted litigation of the above claims, the United States and BioScrip have reached a full and final mutually agreeable resolution of these claims;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. BioScrip consents to this Court's exercise of personal jurisdiction over BioScrip.

- 2. BioScrip admits and acknowledges the following facts:
  - a. From November 2005 to May 2012, BioScrip contracted with Novartis to dispense Exjade as part of Novartis's "Exjade Patient Assistance and Support Services" network ("EPASS"). During this period, BioScrip was one of three specialty pharmacies permitted to dispense Exjade as part of EPASS (the "EPASS pharmacies").
  - b. To prescribe Exjade through EPASS, physicians wrote patient prescriptions on EPASS enrollment forms and submitted those forms to EPASS. Patient prescriptions submitted to EPASS were distributed among the three EPASS pharmacies. EPASS was required (by insurance companies and/or physicians) to refer certain patient prescriptions to specific EPASS pharmacies. Approximately half of the patient prescriptions received by EPASS were not designated for a particular pharmacy by insurers or physicians. The distribution of those patients (the "undesignated patient referrals") among the three EPASS pharmacies was made at the direction of Novartis.
  - c. Upon receiving a patient referral from EPASS, BioScrip would dispense the initial order of Exjade and, if the patient agreed, any refills of Exjade. For refills, BioScrip understood that, even if a physician had prescribed such a refill, third-party payors required patient consent before BioScrip could ship a refill to an Exjade patient.
  - d. Exjade patient referrals had economic value to BioScrip because having more Exjade patients resulted in higher sales revenue, additional dispensing fees, and additional rebates.
  - e. Pursuant to its contract with Novartis, BioScrip collected data on the reasons that patients stopped ordering Exjade refills and provided such data to Novartis on a monthly basis. Based on this data, BioScrip knew that side effects and doctors' orders to discontinue therapy were among the most common reasons that Exjade patients stopped ordering refills.
  - f. In February 2007, Novartis informed BioScrip that the level of refill orders among BioScrip's Exjade patients was below the refill levels achieved by the

- other two EPASS pharmacies.
- g. In February 2007, Novartis demanded that BioScrip implement a Performance Improvement Plan ("PIP") due to its low refill levels relative to the other EPASS pharmacies. Specifically, Novartis informed BioScrip that it had to increase its refill levels or Novartis would cut off the flow of undesignated patient referrals to BioScrip and, potentially, remove BioScrip from EPASS.
- h. In response, and to avoid losing access to patient referrals, BioScrip launched an intensive effort to (i) increase overall patient orders for Exjade refills, and (ii) "restart" many patients who had stopped ordering Exjade. To achieve that goal, BioScrip hired or reassigned a group of staff including a licensed practical nurse ("LPN"), two or three medical assistants, and several customer service representatives to work exclusively on Exjade (collectively, the "Exjade Team"). BioScrip directed the Exjade Team to call many patients to encourage them to order refills and to encourage many patients who had stopped ordering refills to "restart" Exjade.
- i. The efforts of the Exjade Team resulted in significant increases in Exjade refill levels at BioScrip by September 2007, the refill levels at BioScrip were higher than at the other two EPASS pharmacies. Recognizing the improvement in refill levels at BioScrip, Novartis did not cut off the flow of undesignated patient referrals or remove BioScrip from EPASS, but continued to direct patient referrals, including undesignated patient referrals, to BioScrip.
- j. BioScrip developed a protocol for the Exjade Team to call patients to encourage many patients to order refills and to encourage many patients who had stopped ordering refills to restart Exjade, which BioScrip named "ScripCare" (or "BioScripCare"). Under that protocol, the Exjade Team made the following kinds of calls: (i) "assessment calls" or "survey calls," during which patients were told that they were receiving clinical counseling and education about Exjade, (ii) calls to patients to encourage many of them to order refills, and (iii) "recovery" calls to encourage many patients who had stopped ordering Exjade to "restart."

- k. In mid-2007, the LPN and the medical assistants on the Exjade Team were given scripts for making calls to new patients to discuss Exjade therapy (the "Call Scripts"). With regard to side effects, the Call Scripts indicated that Exjade therapy could "cause some discomfort initially," but that such discomfort "usually resolves over time."
- In developing ScripCare, BioScrip shared key elements of the protocol with Novartis, including (i) how to discuss Exjade and its side effects with patients, (ii) the sequence of the calls, and (iii) which team members would make the calls. The Exjade marketing team at Novartis provided input on aspects of the ScripCare protocol, including how to discuss potential side effects with Exjade patients. At a January 2008 meeting at Novartis's offices in New Jersey, BioScrip discussed the Call Scripts with Novartis, and Novartis approved those scripts.
- m. BioScrip continued to use the Exjade Call Scripts that Novartis had approved in January 2008 until in or about November 2010. From 2007 to 2010, the activities of the Exjade Team were discussed frequently in the monthly calls and quarterly meetings that representatives from Novartis's Exjade marketing and managed markets teams held with BioScrip. During those discussions, Novartis did not ask BioScrip or recommend for BioScrip to update the Call Scripts; and BioScrip did not advise Novartis that it had made updates to these scripts, since none were made.
- n. In or about July 2007, Novartis began issuing monthly "Exjade Scorecards" to BioScrip that measured, among other things, BioScrip's "adherence" scores. Based on discussions with Novartis, BioScrip knew that the "adherence" scores in the Exjade Scorecards were designed to show how long BioScrip's Exjade patients continued to order refills. BioScrip also knew that, in calculating the adherence scores, Novartis did not exclude patients who stopped ordering refills due to side effects or patients who were directed to stop therapy by their doctors.
- o. In October 2007, Novartis began discussions with BioScrip about a plan to allocate more undesignated patient referrals to BioScrip if, according to the

- adherence scores in the Exjade Scorecards, it remained the highest performer in terms of obtaining refill orders.
- p. As of January 2008, Novartis increased the rebates that BioScrip earned for each Exjade shipment from \$13 to \$20 in recognition of BioScrip's performance and, as BioScrip understood, in order to encourage BioScrip to continue the efforts of its Exjade Team.
- q. In 2008, Novartis actively pursued discussions with BioScrip regarding the plan to provide additional undesignated patient referrals in return for BioScrip's achieving higher adherence scores relative to the other EPASS pharmacies, and BioScrip committed to Novartis to "maintain[] a leadership position in Exjade scorecard performance."
- r. Prior to November 2008, BioScrip agreed to a new patient allocation plan proposed by Novartis, which linked the percentage of undesignated patient referrals for BioScrip to its refill rates as measured by the Exjade Scorecard.
- s. Under that plan, Novartis allocated 60% of all undesignated patients to BioScrip for the first half of 2009 because, according to the September 2008 Exjade Scorecard, BioScrip had generated the highest refill rates among the three EPASS pharmacies. For the second half of 2009, Novartis allocated 40% of undesignated patients to BioScrip based on its high refill rates in early 2009.
- t. In 2008, Novartis also began to offer BioScrip "performance rebates" for Exjade. From 2008 to 2010, the "performance rebates" were conditioned on BioScrip meeting or exceeding quarterly shipment goals set by Novartis. Novartis provided documents to BioScrip indicating that Novartis set these thresholds based on its national marketing objectives.
- u. In March 2011, BioScrip was placed under a "corrective action" plan by Novartis due to its low refill rates relative to the other EPASS pharmacies and other issues, and stopped receiving undesignated patient referrals.
- v. In response to Novartis's placing it under a corrective action plan, and to regain access to patient referrals and improve its performance, BioScrip

- launched an intensive effort, including changing its Exjade Team's protocol, to "restart" many patients and to encourage many patients to order refills.
- w. By late 2011, BioScrip's refill rates had increased significantly; and, starting in January 2012, Novartis allocated 60% of the undesignated patients referrals to BioScrip based on its higher refill rates relative to the other EPASS pharmacies in late 2011.
- 3. In settlement of the United States' claims against BioScrip in this action, BioScrip shall pay to the United States the sum of eleven million six hundred eighty-five thousand and seven hundred and five dollars and forty-three cent (\$11,685,705.43) (the "Settlement Amount"). BioScrip shall pay the Settlement Amount pursuant to the following schedule: (i) on or before January 15, 2014, BioScrip shall make an initial payment in the amount of two million three hundred thirty-seven thousand and one hundred forty-one dollars (\$2,337,141.00) plus interest, compounded annually at the rate of 3.25%, accruing from the Effective Date of this Stipulation (as defined in paragraph 24 below) to the date of the initial payment; (ii) on or before January 15, 2015, BioScrip shall make a second payment in the principal amount of four million six hundred seventy-four thousand and two hundred eighty-two dollars (\$4,674,282.00), plus interest, compounded annually at the rate of 3.25%, accruing from the Effective Date to the date of the second payment; and (iii) on or before January 15, 2016, BioScrip shall make a final payment in the principal amount of four million six hundred seventy-four thousand and two hundred eightytwo dollars and forty-three ce (\$4,674,282.43), plus interest, compounded annually at the rate of 3.25%, accruing from the Effective Date to the date of the third payment. Further, in connection with the entry of this Stipulation, BioScrip consents to the entry of a judgment against BioScrip and for the United States in the Settlement Amount (a proposed Consent Judgment is attached hereto as Exhibit A).
  - 4. Subject to the exceptions in Paragraph 5 below (concerning excluded claims),

conditioned upon BioScrip's timely payments of the full Settlement Amount pursuant to paragraph 3, the United States, on behalf of itself, its officers, agencies and departments, releases BioScrip, and all of its current and former officers, directors, employees, servants, assigns, attorneys and agents from any civil or administrative monetary claim the United States has 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 or equitable theories of payment by mistake, unjust enrichment, negligence, and fraud, related to the Covered Conduct.

- 5. Notwithstanding the release given in Paragraph 4 of this Stipulation, or any other term of this Stipulation, the following claims of the United States are specifically reserved and are not released by this Stipulation:
  - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
  - b. Any criminal liability;
  - Except as expressly stated in this Stipulation, any administrative liability, including mandatory and permissive exclusion from Federal health care programs;
  - d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and
  - e. Any liability based on obligations created by this Stipulation.
- 6. BioScrip waives and shall not assert any defenses it may have to any federal criminal prosecution or federal 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 federal criminal prosecution or federal 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.

- 7. BioScrip fully and finally releases the United States, and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that BioScrip has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 8. In consideration of (i) execution of this Stipulation by the Relator and (ii) the Relator's releases as set forth in paragraph 9 below, BioScrip and all of its current and former officers, directors, employees, assigns, attorneys, and agents, on behalf of themselves and their heirs, attorneys, agents, successors, and assigns, release the Relator, his heirs, attorneys, agents, successors, and assigns, from any and all claims for any action, event, or conduct related to the Relator's allegations in this Action.
- 9. Conditioned upon BioScrip's full payment of the Settlement Amount, the Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases BioScrip and all of its current and former officers, directors, employees, assigns, attorneys, and agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against BioScrip related to the Relator's allegations in this Action; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover his reasonable expenses and attorneys' fees and costs from BioScrip pursuant to 31 U.S.C. § 3730(d) or be deemed to have released his claims under 31 U.S.C. § 3730(d) for such reasonable expenses and attorneys' fees and costs.
- 10. The Relator shall not object to this Stipulation but agrees and confirms, pursuant to 31 U.S.C. § 3730(c)(2)(B), that the terms of this Stipulation are fair, adequate, and reasonable

under all the circumstances.

- 11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, or any federal or state payer, related to the Covered Conduct; and BioScrip agrees not to resubmit to any Medicare carrier or intermediary or any federal or state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.
- 12. BioScrip agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Specifically, BioScrip shall provide truthful and complete disclosure of all non-privileged documents and information requested by the United States relating to the allegations in the United States's Amended Complaint-in-Intervention. Further, BioScrip agrees to furnish to the United States, upon request, complete and un-redacted 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. Additionally, BioScrip 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.
- 13. Subject to the exceptions in Paragraph 5, in consideration of BioScrip's obligations under this Stipulation, the United States shall promptly file appropriate papers to dismiss without prejudice the claims against BioScrip in the United States's Amended Complaint-in-Intervention after the Court enters this Stipulation and the Consent Judgment attached as Exhibit A. Further, promptly after BioScrip pays the Settlement Amount pursuant to Paragraph 3, the United States shall file a satisfaction of judgment as to the Consent Judgment and the appropriate papers to

dismiss with prejudice the claims against BioScrip in the United States's Amended Complaint-in-Intervention. Provider, however, that the Court shall retain jurisdiction over this Stipulation and the Settling Parties until such time as BioScrip has paid the Settlement Amount pursuant to Paragraph 3 and completed its obligations under Paragraph 12 and until the Court has decided or the Settling Parties have resolved the Relator's claims against Bioscrip for reasonable expenses, attorneys' fees and costs and against the United States for a share of the proceeds of this Settlement.

BioScrip shall be in default of this Stipulation if it fails to make any of the three payments set forth in Paragraph 3, in whole or in part, on or before the due date for such payment. The United States will provide written notice of any default, to be sent by e-mail and first-class mail to one or more of the counsel for BioScrip identified in Paragraph 23. In the event of default, the entire remaining unpaid balance of the Settlement Amount shall be immediately due and payable by BioScrip, and interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance, beginning seven (7) business days after delivery of the notice of default. If the Settlement Amount, with all accrued interest, is not paid in full within seven (7) business days following delivery of the notice of default, BioScrip shall agree to entry of a Consent Judgment in favor of the United States against BioScrip in the amount of the unpaid balance, and the United States, at its option, may (a) rescind this Stipulation and reinstate the claims asserted against BioScrip in its Amended Complaint-in-Intervention in this Action; (b) seek specific performance of the Stipulation; (c) offset the remaining unpaid balance from any amounts due and owing BioScrip 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. BioScrip shall not contest any offset imposed or any collection action undertaken by the United States

pursuant to this paragraph, either administratively or in any Federal or State court. In addition, BioScrip shall pay the United States 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, BioScrip shall not plead, argue, or otherwise raise any defense under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

- 15. BioScrip agrees to the following:
  - a. <u>Unallowable Costs Defined</u>: 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 BioScrip, its present or former officers, employees, and agents in connection with:
    - (1) the matters covered by this Stipulation;
    - (2) the United States's civil investigation of the Covered Conduct;
    - (3) the investigation, defense, and corrective actions undertaken by BioScrip in response to the United States's civil investigation of the Covered Conduct (including attorney's fees);
    - (4) the negotiation and performance of this Stipulation;
    - (5) the payments BioScrip makes to the United States pursuant to this Stipulation and any payments that BioScrip may make to Relator, including costs and attorneys fees; and
    - (6) the negotiation of, and obligations undertaken pursuant to any integrity agreement relating to the Covered Conduct with HHS-OIG to (i) retain an independent review organization to perform annual reviews of required by any such integrity agreement, 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 Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in this Paragraph (*i.e.*, Paragraph 15(a)(6)) that may apply to the obligations undertaken pursuant to any such integrity agreement affects the status of costs that are not allowable based on any other authority applicable to BioScrip.

- b. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by BioScrip, and BioScrip 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 BioScrip or any of its agencies or departments to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: BioScrip 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 BioScrip or any of its agencies or departments, 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. BioScrip agrees that the United States, at a minimum, shall be entitled to recoup from BioScrip 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. The United States reserves its rights to disagree with any calculations submitted by BioScrip or any of its rights to audit, examine, or re-examine BioScrip's books and records to determine that

no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph, and to disagree with any calculations submitted by BioScrip or any of its agencies or departments concerning any Unallowable Costs included in payments previously sought by BioScrip, or the effect of any such Unallowable Costs on the amount of such payments.

- 16. Except as expressly provided to the contrary in this Stipulation, this Stipulation is intended to be for the benefit of the Settling Parties only. The Settling Parties do not release any claims against any other person or entity.
- 17. If within 91 days of the Effective Date or of any payment made under this Stipulation, BioScrip commences any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of BioScrip's debts, or seeking to adjudicate BioScrip as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for BioScrip or for all or any substantial part of its assets, BioScrip agrees as follows:
  - a. BioScrip's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and BioScrip shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) BioScrip's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) BioScrip was insolvent at the time this Stipulation was entered into, or became insolvent as a result of the payments made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to BioScrip.
  - b. If BioScrip'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 United States, at its sole option, may rescind the releases in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against BioScrip for the claims that would otherwise be covered by the releases provided in Paragraph 5 above. BioScrip agree that (i) any such claims, actions, or proceedings

brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this paragraph, and BioScrip shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) BioScrip shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 60 calendar days of written notification to BioScrip that the releases have been rescinded pursuant to this paragraph; and (iii) the United States has a valid claim against BioScrip in the amount of eleven million six hundred eighty-five thousand and seven hundred and five dollars and forty-three cents (\$11,685,705.43), and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this paragraph, as well as in any other case, action, or proceeding.

- c. BioScrip acknowledges that its agreements in this paragraph are provided in exchange for valuable consideration provided in this Stipulation.
- 18. BioScrip agrees that it waives and shall not seek payment of any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims submitted in connection with the Covered Conduct.
- 19. 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, it shall be deemed to have been drafted by the Settling Parties, and shall not, therefore, be construed against any Settling Party for that reason in any subsequent dispute.
- 20. Each of the Settling Parties shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation;

provided, however, nothing in this Stipulation shall preclude Relator from seeking to recover his/her expenses or attorney's fees and costs from BioScrip, pursuant to 31 U.S.C. § 3730(d), or BioScrip from opposing such a request by the Relator.

- 21. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and entities indicated below.
- 22. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.
- 23. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by express courier and by e-mail transmission, followed by postage-prepaid mail, to the following representatives:

## TO THE UNITED STATES:

Li Yu, Rebecca C. Martin, and Ellen M. London Assistant United States Attorneys Southern District of New York 86 Chambers Street, 3<sup>rd</sup> Floor New York, NY 10007

E-mail: Li.Yu@usdoj.gov

Rebecca.Martin@usdoj.gov Ellen.London@usdoj.gov

## TO THE RELATOR:

Shelley Slade, Esq.
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Washington, D.C. 20017
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## TO BIOSCRIP:

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New York, New York 10036
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24. The effective date of this Stipulation is the date upon which this Stipulation is entered by the Court (the "Effective Date).

For the	United States:	<u> </u>	or Bio	S <u>crip</u> :
Dated:	January, 2014	D	ated:	January <u>6</u> , 2014
	PREET BHARARA United States Attorney			POLSINELLI PC
By	•		By:	
27.	LI YU REBECCA C. MARTIN ELLEN M. LONDON Assistant United States Attorneys 86 Chambers Street, 3 <sup>rd</sup> Floor New York, New York 10007		-3.	MARY CLARE BONACCORSI, ESQ. MARK GORAN, ESQ. 161 N. Clark Street, Suite 4200 Chicago, IL 60601
				DAY PITNEY LLP
Dated:	January, 2014  DEPARTMENT OF HEALTH AND HUMAN SERVICES		Ву:	JAMES R. DEVITA, Esq. 7 Times Square New York, New York 10036
Ву	:			
	ROBERT K. DECONTI Assistant Inspector General for Legal A Office of Counsel to the Inspector Gene Office of the Inspector General		Ву:	BIOSCRIP, INC.
For the	Relator:			
Dated:	December, 2013  VOGEL, SLADE & GOLDSTEIN, LLP		By:	RUSSEL CORVESE
				Senior Vice President
Ву	SHELLEY R. SLADE, Esq.			
	DAVID KESTER	SO ORD	ERED	:
				N MCMAHON TES DISTRICT JUDGE

For the United States:	For Bio	Scrip:
Dated: January, 2014	Dated:	January <u>6</u> , 2014
PREET BHARARA United States Attorney		POLSINELLI PC
By:  LI YU  REBECCA C. MARTIN  ELLEN M. LONDON  Assistant United States Attorneys 86 Chambers Street, 3 <sup>rd</sup> Floor New York, New York 10007  Dated: January, 2014  DEPARTMENT OF HEALTH AND HUMAN SERVICES		MARY CLARE BONACCORSI, Esq MARK GORAN, Esq. 161 N. Clark Street, Suite 4200 Chicago, IL 60601  DAY PITNEY LLP  JAMES R. DEVITA, Esq. 7 Times Square New York, New York 10036
By:		Kimberlee C. Seak General Coursel
By: SHELLEY R. SLADE, Esq.		RUSSELL CORVESE Senior Vice President
DAVID KESTER		N MCMAHON TES DISTRICT JUDGE

For the	<u>United States</u> :	For Bio.	Scrip:
Dated:	January, 2014	Dated:	January <u>6</u> , 2014
	PREET BHARARA United States Attorney		POLSINELLI PC
Ву	LI YU REBECCA C. MARTIN ELLEN M. LONDON Assistant United States Attorneys 86 Chambers Street, 3 <sup>rd</sup> Floor New York, New York 10007	Ву:	MARY CLARE BONACCORSI, Esq. MARK GORAN, Esq. 161 N. Clark Street, Suite 4200 Chicago, IL 60601  DAY PITNEY LLP
Dated:	January, 2014  DEPARTMENT OF HEALTH AND HUMAN SERVICES	Ву:	JAMES R. DEVITA, ESQ. 7 Jimes Square
Ву	ROBERT K. DECONTI Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of the Inspector General	Ву:	New York, New York 10036  BIOSCRIP, INC.
For the	Relator:		
Dated:	December, 2013  VOGEL, SLADE & GOLDSTEIN, LLP	Ву:	RUSSELL CORVESE Senior Vice President
Ву	SHELLEY R. SLADE, Esq.		
	DAVID KESTER SO OF	RDERED	:
			N MCMAHON

For the	<u>United States</u> :		For Bio	<u>Scrip</u> :
Dated:	January, 2014		Dated:	January <u>6</u> , 2014
•	PREET BHARARA United States Attorney			POLSINELLI PC
Ву:	LI YU REBECCA C. MARTIN ELLEN M. LONDON Assistant United States Attorneys 86 Chambers Street. 3 <sup>rd</sup> Floor New York, New York 10007		By:	MARY CLARE BONACCORSI, Esq. MARK GORAN, Esq. 161 N. Clark Street, Suite 4200 Chicago, IL 60601
Dated:	January 2014			DAY PITNEY LLP
	DEPARTMENT OF HEALTH AND HUMAN SERVICES		Ву:	JAMES R. DEVITA, Esq. 7 Times Square New York, New York 10036
By:	ROBERT K. DECONTI			•
	ROBERT K. DECONTI Assistant Inspector General for Legal A Office of Counsel to the Inspector Gen Office of the Inspector General		By:	BIOSCRIP. INC.
For the	<u>Relator</u> :			
Dated:	December 2013  VOGEL, SLADE & GOLDSTEIN, LLP		By:	RUSSELL CORVESE
	TOTAL DEADL & GOLDSTEIN, ELI			Senior Vice President
Ву:	SHELLEY R. SLADE, Esq.			
	DAVID KESTER	SO ORE	ERED:	
				MCMAHON ES DISTRICT JUDGE

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25. This Stipulation constitutes the complete agreement between the Settling Parties.

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This Stipulation may not be amended except by written consent of the Settling Parties.			
For the	United States:	For Bio.	S <u>crip</u> :
Dated:	January <u>6</u> , 2014	Dated:	January, 2014
	PREST BHARARA United States Attorney		Polsinelli PC
By Dated;	LI YU REBECCA C. MARTIN ELLEN M. LONDON Assistant United States Attorneys 86 Chambers Street, 3rd Ploor New York, New York 10007	Ву	MARY CLARE BONACCORSI, Esq. MARK GORAN, Esq. 161 N. Clark Street, Suite 4200 Chicago, IL 60601 Day Priney LLP
Ву	DEPARTMENT OF HEALTH AND HUMAN SERVICES  POBLIT Y. Deloute ROBERT K. DECONTI	Ву:	JAMES R. DEVITA, Esq. 7 Times Square New York, New York 10036
	Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of the Inspector General	By:	BioScrip, Inc.
For the Relator:			
Dated:	December 23, 2013	Ву:	RUSSELL CORVESE
	The man Column to Columnia I I D		KUNSELL CUKYESD

HON. COLEEN MCMAHON
UNITED STATES DISTRICT JUDGE

Senior Vice President

SHELLEY R. SLADE, Esq.