

SETTLEMENT AGREEMENT

I. PARTIES

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 of the Department of Health and Human Services (“OIG-HHS”), the TRICARE Management Activity (“TMA”), and the United States Office of Personnel Management (“OPM”) (collectively the “United States”); Joe Strom (“Relator”); and Scios, Inc. and Johnson & Johnson (collectively, “Defendants”). Collectively, all of the above will be referred to as “the Parties.”

II. RECITALS

A. Johnson & Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. Scios is a Delaware corporation and a subsidiary of Johnson & Johnson. At all relevant times, Scios was headquartered in the Northern District of California and distributed, marketed, and sold pharmaceutical products in the United States, including the drug Natrecor®.

B. On July 22, 2005, Relator filed a *qui tam* action in the United States District Court for the Northern District of California captioned *United States ex rel. Strom v. Scios, Inc. and Johnson & Johnson, Inc.*, No. C 05-3004 CRB, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The United States intervened in the Civil Action on February 11, 2009, and filed the United States’ Complaint on June 11, 2009 (“United States’ Complaint”).

C. On October 5, 2011, Scios pleaded guilty to introducing a misbranded drug, Natrecor®, into interstate commerce in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C §§ 331(a) & 333(a)(1) (the “Plea Agreement”). *United States v. Scios, Inc.*, No. CR 11-461 CRB. The District Court sentenced Scios to pay an \$85 million criminal fine.

D. The United States contends that Defendants caused claims for payment for Natrecor® and ancillary services to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”). The United States further alleges that Defendants caused claims for payment for Natrecor® and ancillary services to be

submitted to the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”), and the Federal Employees Health Benefits Program, 5 U.S.C. §§ 8901-8914 (“FEHBP”).

D. The United States contends that it has certain civil claims against Defendants arising from their conduct in causing the submission of claims to Medicare, TRICARE, and FEHBP as specified in the United States’ Complaint. That conduct is referred to herein as the “Covered Conduct.”

E. The United States also contends that it has certain administrative claims against Defendants as specified in Paragraphs III.4 through III.6, below, for engaging in the Covered Conduct.

F. This Agreement is made in compromise of disputed claims. This Agreement is not an admission of facts or liability by Defendants, nor a concession by the United States that its claims are not well-founded. Defendants expressly deny the allegations of the United States and Relator as set forth herein and in the Civil Action and deny that they engaged in any wrongful conduct in connection with the Covered Conduct, with the exception of such admissions that were made in connection with the Plea Agreement.

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

H. 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:

III. TERMS AND CONDITIONS

1. Defendants shall pay to the United States one hundred eighty-four million dollars (\$184,000,000), plus interest at the rate of 1.375 percent per annum from June 17, 2012, and continuing until and including the day of payment (collectively, the “Settlement Amount”) by electronic funds transfer pursuant to written instructions from the United States no later than fifteen (15) business days after the Effective Date of this Agreement. The Settlement Amount

shall constitute a debt immediately due and owing to the United States on the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph III.7 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases Defendants, together with their current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and their current and former owners, officers, directors, employees, and affiliates; and the predecessors, successors, transferees, and assigns of any of them, 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 which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, disgorgement and fraud.

3. Subject to the exceptions in Paragraph III.7 below (concerning excluded claims) and Paragraph III.16 below (concerning Relator's Share and reasonable fees, expenses, and costs), and conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendants, together with their predecessors, current and former parent corporations, transferees, divisions, affiliates, subsidiaries, successors, and assigns, and their current or former owners, officers, directors, and employees, representatives, agents, servants, consultants, and attorneys, individually or collectively, from any and all civil monetary claim Relator has or may have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and for 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, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, or under any federal or state statute

or regulations, or otherwise that Relator has standing to bring which Relator may now have or claim to have against Defendants or related entities, arising in any way out of or connected in any way with the facts, claims, and circumstances alleged in, arising under, or arising from the filing of, the Civil Actions, or from any other past activities and actions of the Defendants or related entities with the following exception: Relator and Relator's counsel do not release the Defendants or related entities for any claims they may have for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d).

4. In consideration of the obligations of Defendants in this Agreement and the Corporate Integrity Agreement entered into between OIG-HHS and Johnson & Johnson, and conditioned upon Defendants' full payment of the settlement amount, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Defendants 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, or against Scios under 42 U.S.C. § 1320a-7(b)(1) based on Scios' guilty plea referenced in Paragraph II.C above, except as reserved in Paragraph III.7 (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 Defendants from Medicare, Medicaid, and all 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 or practices, for which claims have been reserved in Paragraph III.7 below.

5. In consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon Defendants' full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Defendants and their predecessors, and their current and former divisions, parents, affiliates, subsidiaries, successors, and assigns, and their current and

former directors, officers, and employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph III.7 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude Defendants 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 TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.7, below.

6. In consideration of the obligations of Defendants in this Agreement, and conditioned upon Defendants' full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against Defendants and their predecessors, and their current and former divisions, parents, affiliates, subsidiaries, successors, and assigns, and their current and former directors, officers, and employees, under 5 U.S.C. § 8902a or 5 C.F.R. Part 890, Subpart J, or Part 919 for the Covered Conduct, except as reserved in Paragraph III.7 (concerning excluded claims), below, and as reserved in this Paragraph. OPM expressly reserves all rights to comply with any statutory obligations to debar Defendants from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. 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 III.7, below.

7. Notwithstanding any term of this Agreement, the following claims of the United States are specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Defendants and the Relator):

- 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 such obligations as are created by this Agreement;
- f. 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 failure to deliver goods or services due; or
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but 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). In connection with this Agreement and the Civil Action, Relator and his heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, nor any dismissal of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his claim(s).

9. Defendants waive and shall not assert any defenses Defendants 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 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.

10. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants 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.

11. In consideration of the obligations of the Relator set forth in this Agreement, Defendants, on behalf of themselves, their predecessors, and their current and former parent corporations, transferees, divisions, affiliates, subsidiaries, successors, and assigns, and their current or former officers, directors, and employees, fully and finally release, waive, and forever discharge Relator and his heirs, successors, attorneys, agents, and assigns from any claims or allegations that Defendants have asserted or could have asserted arising from the Covered Conduct or related to the initiation, investigation, and/or prosecution of the Civil Action by the Relator or his attorneys, except as they relate to a claim by Relator for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d).

12. 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 other state or Federal carrier or payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare carrier or intermediary or any other state or Federal carrier or payer any previously denied claims related to the Covered Conduct, and agree not to appeal any such denials of claims.

13. Defendants agree 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 Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with the

following are “Unallowable Costs” for government contracting purposes and under the Medicare Program, Medicaid Programs, TRICARE Program, and FEHBP:

- (i) the matters covered by this Agreement and the Plea Agreement;
- (ii) the United States’ audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (iii) Defendants’ investigation, defense, and corrective actions undertaken in response to the United States’ audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys’ fees);
- (iv) the negotiation and performance of this Agreement and the Plea Agreement;
- (v) the payments Defendants make or have made to the United States pursuant to this Agreement, the Plea Agreement, and any payments that Defendants may make to Relator, including costs and attorneys’ fees; and
- (vi) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to OIG-HHS. However, nothing in this Paragraph III.13(a)(vi) 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 Defendants.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Defendants further agree that within 90 days of the Effective Date of this Agreement they 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 Defendants or any of their 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. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants 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 Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants or any of their 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 Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. 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 III.2, above, and Paragraph III.15 (waiver for beneficiaries paragraph), below.

15. Defendants agree that they waive 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.

16. Upon receipt of the payment described in Paragraph III.1, above, the Parties shall promptly sign and file a Joint Stipulation of Dismissal in the Civil Action pursuant to Rule 41(a)(1) dismissing with prejudice all claims asserted in the United States' Complaint subject to the terms and conditions of this Agreement, and dismissing remaining claims, if any, asserted in the Civil Action with prejudice as to Relator and without prejudice as to the United States. However, the following claims shall not be dismissed until they are settled, adjudicated, or otherwise resolved: (i) Relator's claims for a Relator's Share of the Settlement Amount pursuant to 31 U.S.C. § 3730(d)(1); and (ii) Relator's claims for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d)(1).

17. 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.

18. 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.

19. 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 Northern District of California, except that disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA. 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.

20. 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.

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

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

23. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

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

THE UNITED STATES OF AMERICA

JOSHUA B. EATON
United States Attorney
Acting Under Authority Conferred by 28 U.S.C. §515

By:

Sara Winslow

Dated: 11/1/13

SARA WINSLOW
THOMAS R. GREEN
Assistant United States Attorney
United States Attorney's Office
Northern District of California

STUART F. DELERY
Assistant Attorney General

By:

Michael D. Granston

Dated: 10/29/2013

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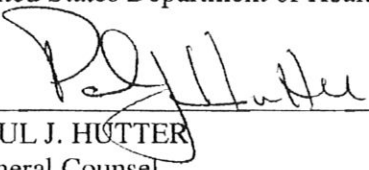
By: Robert K. DeConti Dated: 10/31/13
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
United States Department of Health and Human Services

By: _____ Dated: _____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

By: _____ Dated: _____
SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance Operations
United States Office of Personnel Management

By: _____ Dated: _____
J. DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

By: _____ Dated: _____
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
United States Department of Health and Human Services


By:  _____ Dated: 9/30/13
PAUL J. HUTTEN
General Counsel
TRICARE Management Activity
United States Department of Defense


By: _____ Dated: _____
SHIRLEY R. PATTERSON
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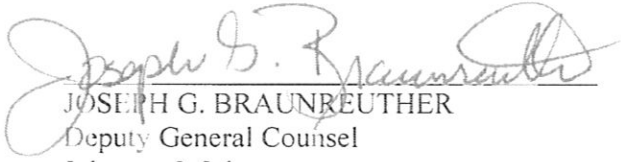
By: _____ Dated: _____
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
United States Department of Health and Human Services

By: _____ Dated: _____
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

By:  _____ Dated: 9/30/13
SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance Operations
United States Office of Personnel Management

By:  _____ Dated: 9/30/2013
J. DAVID COPE
Debarring Official
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United States Office of Personnel Management

DEFENDANTS

By: 
JOSEPH G. BRAUNREUTHER
Deputy General Counsel
Johnson & Johnson

Dated: 10/31/13

By: _____
JOHN M. POTTER, ESQ.
Quinn Emanuel Urquhart & Sullivan, LLP
Counsel for Scios, Inc.

Dated: _____

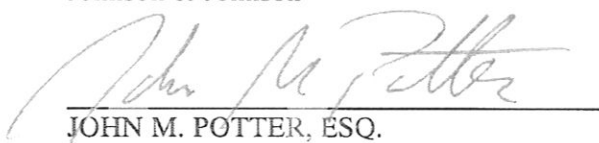
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By:

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Dated: _____

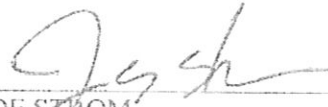
By:




JOHN M. POTTER, ESQ.
Quinn Emanuel Urquhart & Sullivan, LLP
Counsel for Scios, Inc.

Dated: 10/31/13

RELATOR

By: 
JOE STROM
Relator

Dated: 10/15/13

By: 
MARCELLA AUERBACH, ESQ.
Nolan, Auerbach & White
Counsel for Relator

Dated: 10/16/13