

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (“Agreement”) is entered into, between and among the following, through their authorized representatives: (1) the United States of America, acting through the United States Department of Justice and the United States Attorney’s Office for the Eastern District of Pennsylvania, and on behalf of (a) the Office of the Inspector General (“OIG-HHS”) of the United States Department of Health and Human Services (“HHS”), (b) the United States Department of Defense TRICARE Management Activity (“TMA”), and (c) the United States Department of Veterans Affairs (“VA”) (collectively “the United States”); (2) Synthes, Inc. (“Synthes”); and (3) Norian Corporation (“Norian”). Synthes and Norian are hereinafter collectively referred to as “the Companies.” The United States, Synthes, and Norian are hereinafter collectively referred to as “The Parties.”

II. PREAMBLE

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

A. Synthes is a business corporation that is organized under the laws of the State of Delaware, with its principal place of business located at West Chester, Pennsylvania. Synthes is a multi-national medical device manufacturing corporation. Synthes’ business units include a Spine unit (also known as Synthes Spine and focused on devices for the spine) and a Trauma unit (also known as Synthes U.S.A. and focused on devices for non-spine, non-head areas of the body).

B. Norian is a wholly owned subsidiary of Synthes, with its principal place of business located at West Chester, Pennsylvania.

C. At all relevant times the Companies developed, manufactured, distributed, marketed and sold medical devices in the United States. Such devices included significant risk medical devices (within the meaning of 21 U.S.C. § 321(h)(1) and 21 C.F.R. § 812(m)(1)) that were sold under the trade names of Norian XR and Norian SRS (together referred to as the “Covered Devices”).

D. On such date as the Court may determine, Synthes will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (“the Synthes Plea Agreement”) to a Superseding Information (waiving prosecution by indictment) to be filed in United States of America v. Synthes, Inc., Criminal Action No. 09-403-02 (Eastern District of Pennsylvania) (the “Synthes Criminal Action”) that will charge Synthes with one count of misdemeanor violations of Title 21, United States Code, Sections 331(a) and 333(a)(1), namely, the introduction into interstate commerce of medical devices, Norian XR and Norian SRS, that were adulterated under 21 U.S.C. § 351(f)(1)(B) and that were misbranded under 21 U.S.C. § 352(f), (o).

E. On such date as the Court may determine, Norian will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (“the Norian Plea Agreement”) to a Superseding Information (waiving prosecution by indictment) to be filed in United States of America v. Norian Corporation, Criminal Action No. 09-403-01 (Eastern District of Pennsylvania) (the “Norian Criminal Action”) that will charge Norian with: (a) one count of felony violation of Title 18, United States Code, Section 371; and (b) 110 misdemeanor counts of violating 21 U.S.C. §§ 331(a) and 333(a)(1) -- namely, introducing into interstate commerce medical devices, Norian XR and Norian SRS, that were adulterated under 21 U.S.C. § 351(f)(1)(B) and misbranded under 21 U.S.C. § 352(f), (o).

F. The United States alleges that the Companies engaged in the following conduct (“the Covered Conduct”) during the period November 1, 2002 through January 1, 2004:

The Companies made and/or disseminated unsubstantiated and/or false representations, directly or by implication, about the safety and efficacy of the Covered Devices, as set forth in the Superseding Informations to be filed in Criminal Action Nos. 09-403-01 and 02, in connection with the use of those devices in vertebral compression fracture surgeries involving thirty-one (31) beneficiaries covered by Medicare, TRICARE, and/or the VA when the use of those devices was not reasonable and necessary, and when such non-indicated use was, on the Norian XR product and/or package labeling, explicitly warned against. As a result of the foregoing conduct, the Companies knowingly caused false or fraudulent claims for the Covered Devices to be submitted to, or purchases to be made by, Medicare, TMA, and the VA in connection with those thirty-one (31) beneficiaries.

G. The United States contends that it has certain civil and administrative claims, as specified in Paragraphs 2, 3, and 4 below, against the Companies for engaging in the Covered Conduct.

H. This Agreement is made in compromise of disputed claims. This Agreement is not an admission of facts or liability by the Companies. With the exception of such admissions that are made in connection with any guilty plea by the Companies in connection with the Synthes Criminal Action and the Norian Criminal Action, the Companies expressly deny the allegations of the United States as set forth herein and deny that the Companies engaged in any wrongful conduct in connection with the Covered Conduct. This Agreement is not a concession by the United States that its claims are not well founded. Neither

this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of any settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by the Companies.

I. To avoid the delay, uncertainty, risk, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein, and in consideration of the mutual promises, covenants, and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties, intending to be legally bound, agree as follows:

1. Synthes agrees to pay to the United States the sum of One Hundred and Thirty Eight Thousand Dollars (\$138,000.00) (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States on the Effective Date of this Agreement. Pursuant to written instructions to be provided by the United States Attorney's Office for the Eastern District of Pennsylvania, Synthes agrees to pay the Settlement Amount to the United States by electronic funds transfer no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to counsel for Synthes and Norian; or (ii) the Court accepts Fed. R. Crim. P. 11(c)1(C) guilty pleas as described in Preamble Paragraphs D and E and imposes the agreed-upon sentences, whichever occurs later.

2. Subject to the exceptions in Paragraph 5 below (concerning claims excluded from this Agreement), and in consideration of the obligations of the Companies that are

set forth in this Agreement, and on condition that Synthes fully pays the Settlement Amount, the United States (on behalf of itself, its officers, agents, departments, and agencies) agrees to release the Companies -- and their current and former parent corporations, affiliates, and subsidiaries; current or former owners, officers, directors, agents, servants, and employees, and the successors and assigns of any of them, except as provided below in this paragraph -- 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; or the common law theories of payment by mistake, unjust enrichment, and fraud. This Agreement does not release the following individuals from any claims identified in this Paragraph: Michael D. Huggins; Thomas B. Higgins; Richard E. Bohner; and John J. Walsh.

3. In consideration of Synthes' obligations in this Agreement and in the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Synthes, and conditioned upon Synthes' full payment of the Settlement Amount and compliance with the terms of a Divestiture Agreement to be entered into between OIG-HHS and Synthes regarding Norian, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Synthes and, except for Norian, its United States subsidiaries under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, or against Synthes under 42 U.S.C. § 1320a-7(b)(1) based on Synthes' agreement to plead guilty to charges in the Synthes Criminal Action referenced above in Paragraph D, except as reserved in Paragraph 5 (concerning excluded claims), below,

and as reserved in this Paragraph. If Synthes fails to comply fully with the provisions of the Divestiture Agreement, or if Norian violates the terms of its exclusion, then all OIG-HHS releases granted in this Paragraph shall be rescinded and have no effect. OIG-HHS expressly reserves all rights to comply with any statutory obligation(s) to exclude Synthes and its subsidiaries from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

4. In consideration of Synthes' obligations as set forth in this Agreement, and conditioned upon Synthes' 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 Synthes and, except for Norian, its United States subsidiaries under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 5 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude Synthes and its subsidiaries from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes 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 5, below.

5. Notwithstanding the releases given in Paragraphs 2, 3, and 4, above, and any other 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 the Companies and any other person or entity:

- a. Any civil, criminal, or administrative 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 personal injury or personal damage or for other consequential damages arising from the Covered Conduct.
- g. Any civil or administrative liability of individuals (including current or former directors, officers, employees, agents, or shareholders of Synthes and/or Norian) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), or who are indicted, charged, or convicted, or who enter into a plea agreement related in any way to the Covered Conduct.

6. The Companies waive and will not assert any defenses that they may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the United States Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. The Companies agree that the Settlement Amount is not punitive in nature or effect for purposes of 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.

7. The Companies fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that the Companies, or any of them, has or have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and/or agents, related to: (a) the Covered Conduct and the United States' investigation and prosecution thereof; and/or (b) the Norian Criminal Action and the Synthes Criminal Action.

8. The Settlement Amount that Synthes must pay by electronic wire transfer pursuant to Paragraph 1 of this Agreement 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 TRICARE carrier or payer, or any State payer, related to the Covered Conduct; and the Companies agree not to resubmit to any Medicare carrier or intermediary or any TRICARE carrier or payer or any State payer any previously denied claims related to the Covered Conduct, and agree not to appeal any such denials of claims.

9. The Companies agree to the following:

a. Unallowable Costs Defined: that 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. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Companies, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts, including with the VA, and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP"):

1. the matters covered by this Agreement and the related plea agreements;

2. the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;

3. the Companies' 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 attorney's fees);

4. the negotiation and performance of this Agreement and the related plea agreements;

5. the payment(s) the Companies make to the United States pursuant to this Agreement, including any costs and attorney's fees; and

6. the negotiation of, and the obligations undertaken pursuant to, the CIA, to:

i. retain an independent review organization ("IRO") to perform annual reviews as described in Section III of the CIA; and

ii. prepare and submit reports to OIG-HHS; however, nothing in this Paragraph 9(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to the Companies. (All costs described or set forth in this Paragraph 9.a are hereafter "Unallowable Costs.")

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

c. Treatment of Unallowable Costs Previously Submitted for Payment. The Companies further agree that within 90 days of the Effective Date of this Agreement they will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA, 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 the Companies 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. The Companies agree that the United States, at a minimum, shall be entitled to recoup from the Companies 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 U.S. Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the Companies or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the Companies 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 reexamine the Companies' books and records to

determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph

10. 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 11 (waiver for beneficiaries paragraph), below, and except as otherwise provided in this Agreement.

11. The Companies 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.

12. Synthes warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and that it shall remain solvent following its payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they: (a) have intended that the mutual promises, covenants, and obligations that are set forth herein constitute a contemporaneous exchange for new value given to Synthes, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to represent, and do represent, a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Synthes was or became indebted, on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

13. Each Party shall bear its own legal and other costs incurred in connection with this matter, including for the preparation and performance of this Agreement.

14. The Companies represent that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion whatsoever.

15. The laws of the United States govern this Agreement. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and/or among them under this Agreement will be the United States District Court for the Eastern District of Pennsylvania, except that: (a) disputes arising under the CIA or the Divestiture Agreement between Synthes and OIG-HHS shall be resolved exclusively under the dispute resolution provisions of the agreement at issue; and (b) disputes relating to any OIG-HHS exclusion of Synthes shall be resolved under the HHS administrative process that applies to exclusions.

16. For purposes of construction, 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.

17. This Agreement constitutes the complete agreement among the Parties with respect to the issues that the Agreement covers. This Agreement may not be amended except by written consent of all of the Parties.

18. The individuals signing this Agreement on behalf of Norian and Synthes represent and warrant that they are authorized by those entities to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

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

20. This Agreement is binding upon the successors, transferees, heirs, and assigns of the Companies.

21. Norian and Synthes each consents to the United States' disclosure to the public of this Agreement and of information about this Agreement, after it has been fully executed.

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

23. Notwithstanding any provision of this Agreement, if the guilty pleas referenced in Preamble Paragraphs D and E are not accepted by the Court or the Court does not impose the agreed-upon sentences for whatever reason, this Agreement shall be null and void at the option of either the United States or Synthes or Norian. If either the United States or Synthes or Norian exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If the Agreement is rescinded, Synthes and Norian waive any affirmative defenses based in whole or in part on the running of the statute of limitations during the period from the Effective Date of this Agreement through thirty (30) days after the effective date of the rescission.

THE UNITED STATES OF AMERICA

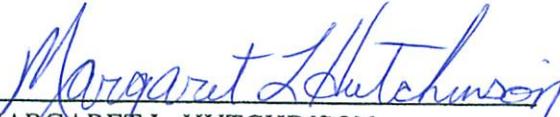
DATED: 9-27-10

BY:


LANE DAVID MEMEGER
United States Attorney
Eastern District of Pennsylvania

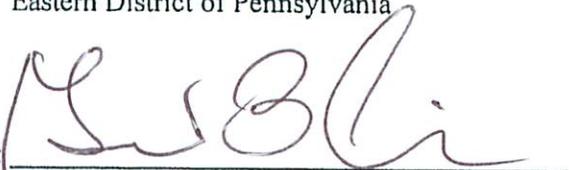
DATED: 9-24-10

BY:


MARGARET L. HUTCHINSON
Assistant United States Attorney
Chief, Civil Division
Eastern District of Pennsylvania

DATED: September 24, 2010

BY:


GERALD B. SULLIVAN
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: September 24, 2010

BY:


COLIN M. HUNTLEY
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

**OFFICE OF INSPECTOR GENERAL,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

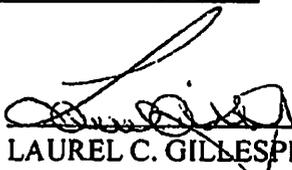
DATED: 9/23/10

BY:  _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human
Services

TRICARE MANAGEMENT ACTIVITY

DATED: 24 Sep 2016

BY: 

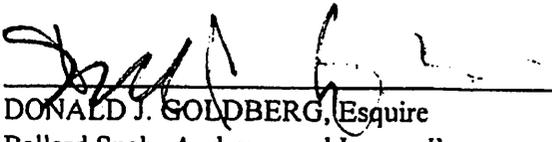
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

SYNTHES, INC.

DATED: 9/20/10

BY: 
MICHEL ORSINGER
President and Chief Executive Officer,
Synthes, Inc.

DATED: 9/22/10

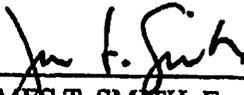
BY: 
DONALD J. GOLDBERG, Esquire
Ballard Spahr Andrews and Ingersoll
Counsel for Synthes, Inc.

NORIAN CORPORATION

DATED: 9/20/2010

BY: 
MICHEL ORSINGER
President
Norian Corporation

DATED: 9/22/10

BY: 
JAMES T. SMITH, Esquire
Blank Rome LLP
Counsel for Norian Corporation