

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively, the “United States”); the Commonwealth of Massachusetts (the “Commonwealth”), acting through the Medicaid Fraud Division of the Office of Attorney General and on behalf of the Executive Office of Health and Human Services (“EOHHS”), limited to its role as the single state agency for Medicaid (“MassHealth”); Johnson & Johnson, DePuy Synthes, Inc. and DePuy Synthes Sales, Inc. (collectively, “DePuy”); and Aleksej Gusakovs (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. DePuy Synthes, Inc. (“DePuy Synthes”) is a Delaware corporation, with a principal office address of 700 Orthopaedic Drive, Warsaw, Indiana, and headquarters at 325 Paramount Drive, Raynham, Massachusetts. DePuy Synthes is a manufacturer of medical devices and supplies and regularly sells its products in the Commonwealth of Massachusetts. DePuy Synthes, Inc. is a wholly-owned subsidiary of Johnson & Johnson. Johnson & Johnson is a New Jersey Corporation with its principal executive offices in New Brunswick, New Jersey.

B. DePuy Synthes Sales, Inc. (“DePuy Synthes Sales”) is a Massachusetts corporation with a principal place of business of 325 Paramount Drive, Raynham, Massachusetts 02767. DePuy Synthes Sales is a medical supply company that regularly distributes, markets, and sells products in Massachusetts and maintains full-time employees within Massachusetts. DePuy Synthes Sales is a wholly-owned subsidiary of Johnson & Johnson.

C. On August 11, 2017, Aleksey Gusakovs filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States et al. ex rel. John Doe v. Johnson & Johnson, et al.*, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) and the Massachusetts False Claims Act, M.G.L. c. 12, § 5C (the “Civil Action”). The Relator filed an amended complaint on March 28, 2018. The United States and the Commonwealth intervened in part in the Civil Action against DePuy on September 6, 2022.

D. The United States contends that DePuy caused the submission of false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”) and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

E. The Commonwealth contends that DePuy caused the submission of false claims for payment to Medicaid.

F. The United States and the Commonwealth contend that they have certain civil claims against DePuy for causing the submission of false claims that resulted from violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Massachusetts Medicaid Anti-Kickback Statute, Mass. Gen. Laws c. 11E § 41. More specifically, the United States and the Commonwealth contend that DePuy knowingly and willfully provided free DePuy products, worth over one hundred thousand dollars, to **The Surgeon** to induce him to use DePuy’s products in spine surgeries he performed on Medicare and Medicaid patients in Massachusetts or to reward his usage of DePuy products in such surgeries in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and the Massachusetts Medicaid Anti-Kickback Statute, Mass. Gen. Laws c. 11E § 41.

G. DePuy admits, acknowledges, and accepts its responsibility for the following facts:

(a) From at least July 2013 through February 2018 (the “Relevant Period”), DePuy, acting through its then-employee **Employee #1** and other DePuy sales representatives, gave **The Surgeon** DePuy implants and instruments, including cages, rods, screws, plates, and a modular access and retraction system (“products”). **The Surgeon** used some of the products to conduct spinal surgeries overseas, including in Bahrain, Kingdom of Saudi Arabia, Kuwait, Lebanon, the United Arab Emirates, and Qatar, for certain patients in the Middle East who were not Medicare or Medicaid beneficiaries. The DePuy products that DePuy gave to **The Surgeon** were sometimes not available at the hospitals and/or with the third-party sales distributors in the countries where **The Surgeon** operated overseas. **The Surgeon** typically traveled with the DePuy products that DePuy, acting through **Employee #1** and other sales representatives, gave to him. Neither **The Surgeon**, nor the hospitals he operated at overseas, nor the third-party sales distributors, nor anyone else, paid DePuy for those products that **The Surgeon** implanted into patients or otherwise used in surgery.

(b) During the Relevant Period, **The Surgeon** performed more than twenty surgeries over the course of multiple trips to six countries, specifically, Bahrain, Kingdom of Saudi Arabia, Kuwait, Lebanon, the United Arab Emirates, and Qatar. In many of these surgeries, **The Surgeon** used certain of the DePuy products, worth thousands of dollars, that **Employee #1** and other DePuy sales representatives had provided to him.

(c) DePuy did not track the products that it gave to **The Surgeon** in the United States for use in surgeries overseas. DePuy did not request or receive payment from **The Surgeon** or the hospitals or the third-party sales distributors in the countries where **The Surgeon** operated overseas

for the DePuy products that DePuy gave to [The Surgeon] in the United States and that he used in certain surgeries overseas.

(d) During the Relevant Period, and continuing for at least a year, [The Surgeon] used DePuy products in his spinal surgeries in Boston, Massachusetts, including surgeries for Medicare and Medicaid beneficiaries for which Medicare and Medicaid paid claims.

The foregoing conduct in paragraphs F and G are hereinafter referred to as the “Covered Conduct.”

H. With the exception of the Covered Conduct, DePuy expressly denies the claims arising from the allegations of the Relator as set forth in the Civil Action against DePuy in paragraphs 68 through 90 and in Counts Six, Seven, Eight, Nine, Ten and Eleven of the Amended Complaint.

I. DePuy has been credited in this settlement under the Department of Justice’s guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112.

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

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. DePuy shall pay to the United States and the Commonwealth \$9,750,000.00, plus interest at a rate of 4.25% per annum from November 2, 2022, and continuing through the date of payment (“Settlement Amount”), no later than fifteen days after the Effective Date of this Agreement. Of the Settlement Amount, \$5,416,666.67 is restitution. DePuy will pay the Settlement Amount as follows:

- (a) DePuy will pay the United States \$7,234,001.91 plus interest (“Federal Settlement Amount”), of which \$4,018,889.95 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office.
- (b) DePuy will pay the Commonwealth \$2,515,998.09 plus interest (“Commonwealth Settlement Amount”), of which \$1,397,776.72 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the Massachusetts Attorney General’s Office.

2. Conditioned upon the United States receiving the Federal Settlement Amount and as soon as feasible after receipt, the United States shall pay \$1,374,460.36 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer (Federal Relator’s Share).

3. Conditioned upon the Commonwealth receiving the Commonwealth Settlement Amount from DePuy, and as soon as feasible after receipt, the Commonwealth shall pay, \$478,039.64 plus a pro rata share of the accrued interest at the rate set forth above to Relators by electronic funds transfer (Commonwealth Relator’s Share).

4. DePuy shall pay, pursuant to 31 U.S.C. § 3730(d) and M.G.L. c. 12, § 5F, to Relator a total of \$209,968.50 for expenses, attorneys' fees, and costs no later than thirty (30) calendar days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions provided by Relator.

5. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and upon the United States’ receipt of the Federal Settlement Amount, the United States releases DePuy from any civil or administrative monetary claim the United States has 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.

6. Subject to the exceptions in Paragraph 8 (concerning reserved claims), and conditioned upon the Commonwealth's receipt of the Commonwealth Settlement Amount, the Commonwealth releases DePuy from any civil or administrative monetary claim the Commonwealth has for the Covered Conduct under the Massachusetts False Claims Act, M.G.L. c. 12, § 5A, *et seq.*; M.G.L. c. 118E, §§ 40, 41, and 44; the overpayment provisions of 130 C.M.R. §§ 450.237, 450.260(A), 450.260(I); or the common law theory of unjust enrichment.

7. Conditioned upon DePuy's full payment of the Settlement Amount, and the amount referred to in Paragraph 4, above, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases DePuy from any civil monetary claim the Relator has on behalf of the United States or the Commonwealth for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Massachusetts False Claims Act, M.G.L. c. 12, §§ 5A-5O, and from all liability, claims, demands, actions, or causes of action 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 Relator, his heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action, including claims for reasonable expenses, attorneys' fees, and costs under 31 U.S.C. § 3730(d) and M.G.L. c. 12, § 5F; provided, however, that Relator's release of DePuy does not extend to any claims arising from the Relator's allegations in paragraphs 68 through 90 of the Amended Complaint in the Civil Action.

8. Notwithstanding the releases given in Paragraphs 5, 6, and 7 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States and/or the Commonwealth are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or 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;
- e. Any liability based upon obligations created by this Agreement; and
- f. Any liability of individuals.

9. 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). Conditioned upon Relator's receipt of the Federal Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action. Conditioned upon Relator's receipt of the Commonwealth Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the Commonwealth, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under M.G.L. c. 12 § 5A, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

10. DePuy waives and shall not assert any defenses DePuy 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.

11. DePuy 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 DePuy has 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 or the United States' investigation or prosecution thereof.

12. DePuy fully and finally releases the Commonwealth, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that DePuy has asserted, could have asserted, or may assert in the future against the Commonwealth, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

13. DePuy fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that DePuy has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof; provided, however, that DePuy's release of the Relator does not extend to any claims arising from the Relator's allegations in paragraphs 68 through 90, and in Counts Six, Seven, Eight, Nine, Ten and Eleven,

of the Amended Complaint in the Civil Action and the Relator's investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and DePuy agrees not to resubmit to any Medicare or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

15. DePuy 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of DePuy, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s), civil investigation, and criminal investigation of the matters covered by this Agreement;
- (3) DePuy's investigation, defense, and corrective actions undertaken in response to the United States' audit(s), civil investigation, and criminal investigation in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and

- (5) the payment DePuy makes to the United States pursuant to this Agreement and any payments that DePuy may make to Relator, including 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 DePuy, and DePuy 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 DePuy or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: DePuy 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 DePuy 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. DePuy agrees that the United States, at a minimum, shall be entitled to recoup from DePuy 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 DePuy or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on DePuy or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine DePuy's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

16. DePuy agrees to cooperate fully and truthfully with the United States' and Commonwealth's investigation and litigation of individuals [REDACTED] [REDACTED] not released in this Agreement. Upon reasonable notice, DePuy 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. DePuy 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. DePuy does not waive the right to claim attorney work product protection; the United States does not waive the right to seek documents for which DePuy claims attorney work product protection.

17. 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 18 (waiver for beneficiaries paragraph), below.

18. DePuy agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Upon receipt of the payment described in Paragraph 1, above, the United States, the Commonwealth, and the Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal. The Joint Stipulation of Dismissal shall state that: (1) claims for the allegations described in the Covered Conduct are dismissed with prejudice as to the United States and the Commonwealth; (2) all other claims in the Civil Action shall be dismissed without prejudice as to the United States and the Commonwealth; and (3) all claims in the Civil Action shall be dismissed with prejudice as to the Relator, except any claims specifically reserved in paragraph 7 of this Agreement.

20. Subject to Paragraph 4, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

22. 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 District of Massachusetts. 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.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

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

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

26. This Agreement is binding on DePuy's successors, transferees, heirs, and assigns.


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

28. All Parties consent to the United States' and Commonwealth's disclosure of this Agreement, and information about this Agreement, to the public.

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

THE UNITED STATES OF AMERICA

DATED: 01/17/2023

BY: **JESSICA
WEBER**
 Digitally signed by JESSICA
WEBER
Date: 2023.01.17 11:22:02
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JESSICA J. WEBER
ANDREW A. CAFFREY, III
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: _____

BY: _____
BENJAMIN C. WEI
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

JESSICA J. WEBER
ANDREW A. CAFFREY, III
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 1/13/23

BY: _____


BENJAMIN C. WEI
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____


JESSICA J. WEBER
ANDREW A. CAFFREY, III
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: _____

BY: _____

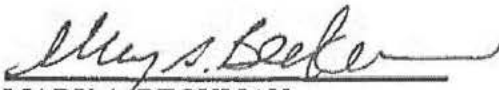
BENJAMIN C. WEI
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 01/13/2023 BY: _____



LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE COMMONWEALTH OF MASSACHUSETTS

DATED: 1/17/2023

BY: 
MARY A. BECKMAN
Acting Secretary
Executive Office of Health and Human Services

DATED: 1/17/23

BY: 
TOBY R. UNGER
Chief, Medicaid Fraud Division
Health Care and Fair Competition Bureau

DEPUY - DEFENDANT

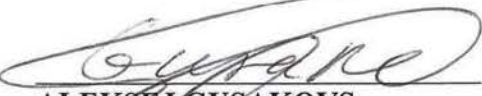
DATED: 1/13/2023


BY: *Laura H. McFalls*
LAURA H. McFALLS
Assistant Corporate Secretary
Johnson & Johnson

DATED: _____

BY: **Seltzer, Mark**
Digitally signed by: Seltzer, Mark
DN: CN = Seltzer, Mark email =
mseltzer@nixonpeabody.com
Date: 2023.01.13 15:09:49 -0500'
MARK D. SELTZER
Partner
Nixon Peabody LLP
Counsel for DePuy

ALEKSEJ GUSAKOV - RELATOR

DATED: 01/13/23 BY: 
ALEKSEJ GUSAKOV

DATED: 1/13/23 BY: 
ROYSTON DELANEY
DELANEY KESTER, LLP
Counsel for Aleksej Gusakov