

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 Defense Health Agency (DHA), acting on behalf of the TRICARE Program, and the Office of Workers Compensation Programs of the United States Department of Labor (DOL-OWCP) (collectively, the “United States”), Medisca, Inc. (“Medisca”), and Doug McMakin (“Relator”), through their authorized representatives. The foregoing hereafter are collectively referred to as “the Parties.”

RECITALS

A. Medisca is a pharmaceutical compounding company that sells active pharmaceutical ingredients (APIs), compounding supplies, and related equipment and services to compounding pharmacies. Medisca is a corporation with its principal place of business in Plattsburgh, New York.

B. On September 21, 2015, relator Doug McMakin filed a qui tam action in the United States District Court for the Eastern District of Texas captioned in relevant part *United States ex rel. Doug McMakin v. Medisca, Inc.*, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). Relator McMakin filed amended complaints on November 13, 2015, and September 16, 2016.

C. The United States contends that Medisca submitted or caused to be submitted claims for payment to the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”) and the DOL-OWCP Program, under the Federal Employees’ Compensation Act, 5 U.S.C. § 8101 et seq. (“FECA”). These programs are referred to collectively in this Agreement as the “Federal Healthcare Programs.”

D. The United States contends that it has certain civil claims against Medisca for: (1) reporting false and inflated Average Wholesale Prices (AWPs) for two API products it sold to

compounding pharmacies—resveratrol (NDC No. 38779-2863) and mometasone furoate (NDC No. 38779-2413) (“Covered Products”) and (2) manipulating the “spread” (i.e., the difference between the AWP and actual acquisition prices) for these Covered Products. The conduct set forth in this Paragraph and the subparagraphs of Paragraph D below is referred to as the “Covered Conduct.” The United States contends as follows:

1. From January 1, 2012, through May 2015, Medisca knowingly caused the submission of false or fraudulent compound prescription claims containing the Covered Products to Federal Healthcare Programs. Medisca knew that Federal Healthcare Programs based their reimbursement for compound prescriptions containing the Covered Products, at least in part, on the AWP for the Covered Products. Medisca knowingly manipulated, established, and reported to various pricing compendia the AWP for the Covered Products in order to increase the reimbursement its pharmacy customers received from Federal Healthcare Programs, which relied on the AWP established and reported by Medisca to determine claim reimbursement amounts. Medisca set, reported, and maintained false and inflated AWP for the Covered Products that were substantially higher relative to the prices at which it sold those ingredients to its pharmacy customers, causing Federal Healthcare Programs to overpay for compound prescriptions.

2. Medisca acquired resveratrol from manufacturers for approximately \$0.37 per gram. It repackaged and sold resveratrol for slightly under \$2 per gram. Medisca set an AWP for resveratrol at approximately \$777 per gram, thereby creating a spread of over \$775 for each gram of resveratrol used in a compound prescription.

3. Medisca acquired mometasone furoate from manufacturers for under \$8 per gram. It repackaged and sold mometasone furoate to compounding pharmacies for over \$1,000 per gram. Medisca established an AWP of over \$7,300 per gram, thereby creating a spread of approximately \$6,300 for each gram of mometasone furoate used in a compound prescription.

4. Medisca induced its pharmacy customers to purchase the Covered Products by creating the inflated spread between the AWP and the actual cost or selling price for each product. Medisca knew that its pharmacy customers placed value and importance on the spread in their purchasing decisions because the larger the spread Medisca created, the greater the profit its pharmacy customers would realize from Federal Healthcare Programs' reimbursement for the Covered Products. Accordingly, Medisca knowingly created large and artificial spreads to induce the purchase of the Covered Products, which Medisca knew would be used in compound prescription claims billed to Federal Healthcare Programs and reimbursed at inflated prices.

E. This Settlement Agreement is neither an admission of liability by Medisca nor a concession by the United States that its claims are not well founded.

F. Relator McMakin 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.

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 Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Medisca shall pay to the United States \$21.75 million plus simple interest accruing at the rate of 4.5% from July 16, 2024, to the date of payment (Settlement Amount), of which \$10.9 million is restitution, no later than ten (10) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount from Medisca and as soon as feasible after receipt, the United States shall pay \$3,425,625 to Relator

McMakin by electronic funds transfer. Payment to Relator McMakin shall be made by electronic funds transfer pursuant to written instructions provided by his counsel.

3. Medisca has entered into a separate agreement, pursuant to 31 U.S.C. § 3730(d), to pay Relator and his attorneys' claims for reasonable expenses, reasonable attorneys' fees and costs arising from the filing of the Civil Action.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon full payment of the Settlement Amount by Medisca, the United States releases Medisca, together with its current and former direct and indirect subsidiaries and divisions; and the predecessors, successors, transferees, and assigns of any of them (collectively, the "Medisca Corporate Released Parties") 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.

5. Subject to the exceptions in Paragraph 7 below, and conditioned upon payment by Medisca of the Settlement Amount and Relator and his attorneys' claims for expenses, fees and costs, Relator McMakin for himself and for his heirs, successors, attorneys, agents, and assigns, releases, acquits, waives, and forever discharges the Medisca Corporate Released Parties, together with its current and former direct and indirect parent corporations and limited liability companies (the "Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; its and their respective current and former corporate owners; other legal entities directly or indirectly controlled by any of the Parents; its and their current and former officers, directors, employees, agents, and attorneys; and the predecessors, successors, transferees, and assigns of any of them (collectively, the "Medisca Released Parties") from any

civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from any and all claims for relief, actions, rights, causes of action, claims, suits, demands, rights, damages (including treble damages and any civil penalties), punitive damages, losses, costs, expenses, fees, accounts, judgments, executions, debts, liabilities, obligations, and any and all other liabilities of any kind, character, or nature whatsoever whether known or unknown, fixed or contingent, suspected or unsuspected, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator otherwise would have standing to bring or ever had or now has against the Medisca Released Parties arising from or related to the Covered Conduct or the claims asserted against Medisca in the Civil Action and Relator's investigation and prosecution thereof, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs, and from all other possible causes of action, known or unknown.

Relator acknowledges that he may discover facts or law different from, or in addition to, the facts or law that he knows or believes to be true with respect to the claims released in this Agreement and agrees nonetheless, that this Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them. Relator expressly acknowledges and agrees that he has the right not to waive claims that are unknown at the time that this Agreement is executed but, nevertheless, Relator waives such claims and his rights under Section 1542 of the California Civil Code and any comparable provisions of other states' and federal law concerning release of unknown claims are expressly waived by Relator. Section 1542 provides:

A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the

release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.

This paragraph (Paragraph 5) is to be interpreted as a general release by Relator McMakin of the Medisca Released Parties.

6. In consideration of the obligations of Medisca set forth in this Agreement, and conditioned upon Medisca's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against the Medisca Corporate Released Parties under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 7 (concerning excluded claims), below. In consideration of the obligations of Medisca set forth in this Agreement, and conditioned upon Medisca's full payment of the Settlement Amount, DOL OWCP's FECA program agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FECA program against the Medisca Corporate Released Parties under 20 C.F.R. § 10.815 except as reserved in this Paragraph and in Paragraph 7 (concerning excluded claims), below. DHA expressly reserves authority to seek to exclude Medisca from the TRICARE Program under 32 C.F.R. §§ 199.9(f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion) and DOL OWCP similarly expressly reserves the right to seek to exclude these entities under 20 C.F.R. § 10.816 (mandatory exclusion), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA, the TRICARE Program and DOL OWCP's FECA program, from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in paragraphs 4, 5 and 6 of this Agreement or any other term of this Agreement, the following claims of the United States 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, 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;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. Medisca fully and finally releases 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 Medisca 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 and the United States' investigation and prosecution thereof.

9. Medisca, its parents, affiliates, subsidiaries, officers, directors, shareholders, and their respective successors, attorneys, agents, and assigns, release Relator McMakin, his attorneys, agents, and assigns, from any claim Medisca has asserted, could have asserted, or may

assert in the future related to the filing, investigation, and prosecution of the Civil Action, and any allegations made by Relator concerning Medisca prior to the Effective Date of this Agreement.

10. Relator McMakin 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 payment described in Paragraph 2, 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.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by TRICARE or any Federal Employees Health Benefits Program (FEHBP) carrier or any state payer, related to the Covered Conduct; and Medisca agrees not to resubmit to any TRICARE or FEHBP carrier 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.

12. Medisca agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Medisca 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) and civil investigation(s) of the matters covered by this Agreement;
- (3) Medisca's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Medisca makes to the United States pursuant to this Agreement and any payments that Medisca may make to Relator, including costs and attorney's fees;

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

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Medisca further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable 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 Medisca 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. Medisca agrees that the United States, at a minimum, shall be entitled to recoup from Medisca 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 Medisca or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Medisca 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 Medisca's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. Medisca agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Medisca 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. Medisca 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.

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 15 (waiver for beneficiaries paragraph), below.

15. Medisca 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.

16. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The Stipulation of Dismissal shall provide that, as to the United States, the action is being dismissed with prejudice as to the Covered Conduct released in the Settlement Agreement and without prejudice as to all other claims. The Stipulation shall provide that as to the Relator, the action is being dismissed with prejudice as to Medisca.

17. With the exception of Medisca's agreement referenced in Paragraph 3, 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 into 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 Eastern District of Texas. 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. 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 Medisca's 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 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: _____

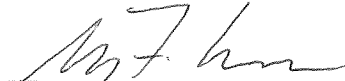
BY: _____

SANJAY M. BHAMBHANI
JOHN DECK
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

JAMES GILLINGHAM
Assistant United States Attorney
United States Attorney's Office
Eastern District of Texas

DATED: 10/9/24



MARY F. KRUGER
Assistant United States Attorney
United States Attorney's Office
Western District of Texas

DATED: 10/09/2024

BY:

BLEY.PAUL.NICHOLAS.1099873821
LAS.1099873821

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for

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY:

JENNIFER VALDIVIESO
Deputy Director for Program and System Integrity
Division of Federal Employees', Longshore and
Harbor Workers' Compensation
Office of Workers' Compensation Programs
United States Department of Labor

DATED: _____

BY: _____
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
JENNIFER VALDIVIESO
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JENNIFER VALDIVIESO
Date: 2024.10.09
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JENNIFER VALDIVIESO
Deputy Director for Program and System Integrity
Division of Federal Employees', Longshore and
Harbor Workers' Compensation
Office of Workers' Compensation Programs
United States Department of Labor

MEDISCA, INC.


DATED: OCT 8, 2024

BY: _____


Mitchell Rubin
Chief Financial Officer
Medisca Inc.

DATED: 10/8/2024

BY: _____


Matthew J. O'Connor
Matthew F. Dunn
COVINGTON & BURLING

DOUG MCMAKIN - RELATOR

DATED: _____

BY: _____

Doug McMakin

DATED: _____

BY: _____

Greg Dykeman

MEDISCA, INC.

DATED: _____

BY: _____
Mitchell Rubin
Chief Financial Officer
Medisca Inc.

DATED: _____

BY: _____
Matthew J. O'Connor
Matthew F. Dunn
COVINGTON & BURLING

DOUG MCMAKIN - RELATOR

DATED: 10-8-24

BY: 
Doug McMakin

DATED: 10/8/24

BY: 
Greg Dykeman