

EXECUTION COPY

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); the Defense Health Agency (DHA), acting on behalf of the TRICARE program; the Department of Defense, acting on behalf of the Defense Logistics Agency (DLA); and the United States Department of Veterans Affairs (VA) (collectively, the “United States”), and Sandoz Inc. (“Sandoz”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Sandoz is a pharmaceutical manufacturer located in Princeton, New Jersey and incorporated in Delaware. Sandoz and its entities manufacture the generic drugs listed on Attachment A to this Agreement.

B. Sandoz has executed a Deferred Prosecution Agreement (“DPA”) with the Antitrust Division of the United States Department of Justice in connection with a four-count criminal Information in the United States District Court for the Eastern District of Pennsylvania (“the Criminal Action”). The Information charged Sandoz with conspiring to suppress and eliminate competition by allocating customers, rigging bids, and fixing and maintaining prices in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

C. The United States contends that Sandoz submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and caused purchases by the VA,

Veterans Health Administration, 38 U.S.C. Chapter 17; and the Department of Defense, DLA (collectively the “Federal Health Care Programs”).

D. The United States contends that it has certain civil claims against Sandoz arising from Sandoz’s alleged conspiracy with competing pharmaceutical manufacturers to fix prices and/or allocate markets (by arrangements on price, supply, and allocation of customers) resulting in payment and receipt of remuneration during the time period of March 1, 2013 through December 31, 2015 for the generic drugs listed in Attachment A (the “Covered Drugs”) in return for arranging for the sale of the Covered Drugs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)(B) (AKS), allegedly resulting in claims submitted to or purchases by Federal Health Care Programs during the same time period. That conduct is referred to below as the “Covered Conduct.”

E. Except to the extent admitted by Sandoz in the DPA in the Criminal Action, Sandoz denies the United States’ allegations in paragraph D.

F. This Settlement Agreement is not an admission of liability by Sandoz nor a concession by the United States that its claims are not well founded.

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. Sandoz shall pay to the United States one hundred eighty five million dollars and zero cents (\$185,000,000.00) (“Settlement Amount”), of which \$113,900,000 is restitution, plus interest on the Settlement Amount at a rate of 1.250 percent accruing from March 1, 2020, no later than seven business days after the Effective Date of this Agreement by electronic funds transfer

pursuant to written instructions to be provided by the U.S. Attorney's Office for the Eastern District of Pennsylvania.

2. Subject to the exceptions in paragraph 5 (concerning excluded claims) below, and conditioned upon Sandoz's full payment of the Settlement Amount, the United States releases Sandoz, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns 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 (FCA); 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.

3. In consideration of the obligations of Sandoz in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and Sandoz, and upon the United States' receipt of full payment of the Settlement Amount (including the interest due under paragraph 1), the 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 Sandoz 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, except as reserved in this paragraph and in paragraph 5 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Sandoz 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 the 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 the obligations of Sandoz set forth in this Agreement, and conditioned upon Sandoz'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 Sandoz, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns 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. DHA expressly reserves authority to exclude Sandoz 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), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in paragraph 7, below.

5. Notwithstanding the releases given in paragraphs 2-4 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 exclusion from Federal health care programs and the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability to states or other government entities for claims arising from the Covered Conduct, including liability to states for the state share of Medicaid;

- 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.

6. Sandoz waives and shall not assert any defenses Sandoz 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.

7. Sandoz 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 Sandoz has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8. 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 or TRICARE contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Sandoz agrees not to resubmit to any Medicare or TRICARE contractor 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.

9. Sandoz 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 Sandoz, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and the DPA;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Sandoz's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any 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 DPA;
- (5) the payment Sandoz makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, Federal Employees Health Benefits Program (FEHBP) or any program of the VA (hereinafter referred to as

Unallowable Costs). However, nothing in 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 Sandoz.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in non-reimbursable cost centers by Sandoz, and Sandoz 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 Sandoz or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, FEHBP or VA Programs.

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

10. Sandoz agrees to incorporate and extend the cooperation obligations imposed in the DPA to Sandoz's cooperation with the United States in the current federal investigation of violations of the FCA and the AKS by other individuals or entities not released in this Agreement, involving the sale of generic drugs in the United States, and any resulting litigation where the United States is a party. Nothing in this paragraph shall be construed as a waiver of any applicable privilege by Sandoz or an agreement to waive any such privilege.

11. 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 elsewhere in this Agreement.

12. Sandoz 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.

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

14. 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.

15. 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 Pennsylvania. 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.

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

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

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


19. This Agreement is binding on Sandoz's successors, transferees, heirs, and assigns.

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

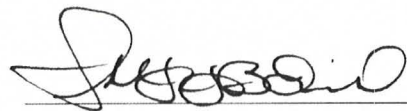
21. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA


DATED: 9/30/21

BY: 
JENNIFER ARBITTIER WILLIAMS
Acting United States Attorney
Eastern District of Pennsylvania

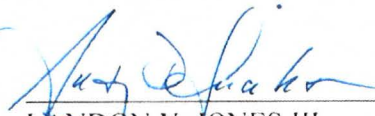
DATED: 9/30/21

BY: 
GREGORY B. DAVID
Chief, Civil Division
Eastern District of Pennsylvania

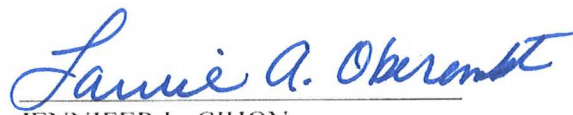
DATED: 9/30/21

BY: 
CHARLENE KELLER FULLMER
Deputy Chief, Civil Division
Eastern District of Pennsylvania

DATED: 9/30/21

BY: 
LONDON Y. JONES III
REBECCA S. MELLEY
ANTHONY D. SCICCHITANO
Assistant United States Attorneys
Eastern District of Pennsylvania

DATED: 9/30/21

BY: 
JENNIFER L. CIHON
LAURIE A. OBEREMBT
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY:

**GREGORY
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GREGORY DEMSKE
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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

DATED: _____

BY:

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

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

DATED: 09/22/2021


BY: BLEY.PAUL.NICHOLAS.1099873821

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

SANDOZ INC.

DATED: 9/28/2021

BY: 
KAREN McDONNELL
VP & General Counsel
Sandoz Inc.

DATED: 9/28/2021

BY: 
SAUL P. MORGENSTERN
Arnold & Porter Kaye Scholer LLP
Counsel for Sandoz Inc.

ATTACHMENT A

Drug
Benazepril-Hydrochlorothiazide
Tobramycin
Fluocinonide ointment
Adapalene
Calcipotriene and Betamethasone Dipropionate
Carbamazepine
Clobetasol
Desonide ointment
Halobetasol cream
Lidocaine ointment
Nystatin triamcinolone cream
Nystatin triamcinolone ointment
Tacrolimus ointment
Temozolomide