

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 Apotex Corp. (Apotex) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Apotex is a company engaged in the sale of pharmaceutical products with its principal place of business in Florida and incorporated in Delaware. Apotex sells among other pharmaceuticals, pravastatin, the generic drug listed on Attachment A to this Agreement.

B. Apotex has executed a Deferred Prosecution Agreement (“DPA”) with the Antitrust Division of the United States Department of Justice in connection with a one-count criminal Information in the United States District Court for the Eastern District of Pennsylvania (“the Criminal Action”). The Information charged Apotex with conspiring to suppress and eliminate competition by agreeing to increase and maintain prices of pravastatin sold in the United States, from in or about May 2013 and continuing through at least December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

C. The United States contends that Apotex 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 Apotex arising from (1) Apotex’s alleged payment and receipt of remuneration through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers between May 1, 2013 through December 31, 2015 for pravastatin listed in Attachment A (the “Covered Drug”) in return for arranging for the sale of the Covered Drug, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)(B) (AKS); and (2) Apotex’s alleged conspiracy with competing pharmaceutical manufacturers to fix prices and/or allocate markets for the Covered Drug, with both of the above resulting in claims for reimbursement submitted to or purchases by Federal Health Care Programs from in or about May 1, 2013 and continuing through December 31, 2015 and further resulting in higher reimbursement and payments by Federal Health Care Programs. That conduct is referred to below as the “Covered Conduct.”

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

F. Except to the extent admitted by Apotex in the DPA in the Criminal Action, Apotex denies the United States’ allegations in Paragraphs C and D.

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. Apotex shall pay to the United States forty-nine million dollars and zero cents (\$49,000,000.00) (“Settlement Amount”), of which \$37,692,307.69 is restitution, plus interest on the Settlement Amount at a rate of 1.25 percent accruing from May 8, 2020, no later than seven

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 reserved claims) below, and conditioned upon Apotex's full payment of the Settlement Amount, the United States releases Apotex, 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 Apotex in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Apotex, and upon the United States' receipt of full payment of the Settlement Amount (including the interest due under Paragraph 1), the OIG-HHS shall 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 Apotex 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 Apotex 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 Apotex set forth in this Agreement, and conditioned upon Apotex'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 Apotex, 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 5 (concerning reserved claims), below. DHA expressly reserves authority to exclude Apotex 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 5, 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;
- 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 non-federal 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. Apotex waives and shall not assert any defenses Apotex 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. Apotex 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 Apotex 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 Apotex 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. Apotex 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 Apotex, 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) Apotex'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 Apotex 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 Apotex.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by Apotex, and Apotex 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 Apotex 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: Apotex 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 Apotex 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. Apotex agrees that the United States, at a minimum, shall be entitled to

recoup from Apotex 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 Apotex or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Apotex 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 Apotex's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

10. Apotex agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Apotex 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 its former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Apotex 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 or matters related thereto that it has undertaken, or that has been performed by another on its behalf.

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. Apotex 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 into 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 Apotex'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 of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

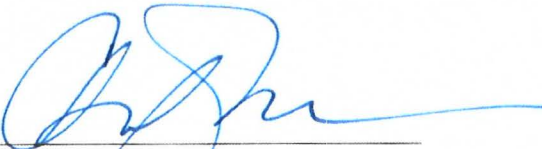
DATED: 9/30/21

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

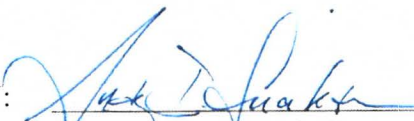
DATED: 9/30/21

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: 
LANDON 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
DEMSKE**

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

Digitally signed by GREGORY
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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: 09/23/2021

BY: _____

BLEY.PAUL.NICHO
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Date: 2021.09.23 10:39:25 -04'00'


for

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

APOTEX CORP.


DATED: September 27, 2021

BY:


PETER HARDWICK
President and CEO
Apotex Corp.

DATED: 09/27/2021

BY:


STEVEN F. CHERRY
APRIL WILLIAMS

DATED: 9/27/2021

BY:


JAMES W. MATTHEWS

Counsel for Apotex Corp.

ATTACHMENT A

Drug	Dosage	NDC-11
Pravastatin	10mg	60505-0168-00
		60505-0168-01
		60505-0168-04
		60505-0168-05
		60505-0168-07
		60505-0168-09
	20mg	60505-0169-01
		60505-0169-02
		60505-0169-05
		60505-0169-07
		60505-0169-09
	40mg	60505-0170-01
		60505-0170-05
		60505-0170-07
		60505-0170-08
		60505-0170-09
	80mg	60505-1323-01
		60505-1323-05
		60505-1323-07
		60505-1323-08
		60505-1323-09