

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), and the Defense Health Agency (DHA), acting on behalf of the TRICARE Program (collectively, the “United States”), and Glenmark Pharmaceuticals Inc., USA (Glenmark) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Glenmark is a distributor and manufacturer of generic pharmaceuticals with headquarters in Mahwah, New Jersey and incorporated in Delaware. Prior to March 21, 2024, Glenmark distributed pravastatin, a generic drug.

B. Glenmark has executed a Deferred Prosecution Agreement (“DPA”) with the Antitrust Division of the United States Department of Justice in connection with a one-count Second Superseding Indictment (“Indictment”) in the case of *United States v. Glenmark Pharmaceuticals Inc. USA*, 20-cr-200-RBS, in the United States District Court for the Eastern District of Pennsylvania (“the Criminal Action”). The Indictment charged Glenmark with conspiring with Teva Pharmaceuticals USA, Inc., Apotex Corp., and others by agreeing to increase and maintain the price of pravastatin and other generic drugs sold in the United States, from in or about May 2013 and continuing at least until December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

C. The United States contends that Glenmark 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”) (collectively the “Federal Health Care Programs”).

D. The United States contends that it has certain civil claims against Glenmark arising from Glenmark’s alleged conspiracy with competing pharmaceutical distributors and/or 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 May 1, 2013 through December 31, 2015 in return for arranging for the sale of pravastatin, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)(B), allegedly resulting in claims submitted to 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 Glenmark in the DPA in the Criminal Action, this Settlement Agreement is neither an admission of liability by Glenmark nor a concession by the United States that its claims are not well founded.

F. Except to the extent admitted by Glenmark in the DPA in the Criminal Action, Glenmark 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. Glenmark shall pay to the United States twenty-five million dollars (\$25,000,000) (Settlement Amount), with interest on the Settlement Amount at a rate of 4.25 percent per annum from May 28, 2024, by electronic funds transfer pursuant to written instructions to be provided by the U.S. Attorney’s Office for the Eastern District of Pennsylvania and in accordance with the

payment schedule set forth in Attachment A. The Settlement Amount and interest on the Settlement Amount constitute restitution.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and subject to Paragraph 4 (concerning disclosure of assets), Paragraph 12 (concerning default), and Paragraph 13 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Glenmark 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.

3. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights 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 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 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;
- f. Any liability based upon obligations created by this Agreement;

- g. Any liability of individuals;
- h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- i. Any liability for failure to deliver goods or services due; and
- j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Glenmark has provided sworn financial disclosures and supporting documents to the United States on three separate occasions dated: September 26, October 12, and November 20, 2023 (together “Financial Disclosures”), and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Glenmark warrants that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Glenmark had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Glenmark’s obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Glenmark on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$1,250,000 or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Glenmark’s previously undisclosed assets. Glenmark agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the

amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, Glenmark waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Glenmark that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on March 23, 2020.

5. Glenmark waives and shall not assert any defenses Glenmark 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.

6. Glenmark 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 Glenmark 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.

7. 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 Glenmark 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.

8. Glenmark 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 Glenmark, 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) Glenmark'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 attorneys' fees);
- (4) the negotiation and performance of this Agreement and the DPA; and
- (5) the payment Glenmark makes to the United States pursuant to this Agreement

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 Glenmark, and Glenmark 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 Glenmark or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Glenmark 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 Glenmark 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. Glenmark agrees that the United States, at a minimum, shall be entitled to recoup from Glenmark 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 Glenmark or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Glenmark 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 Glenmark's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

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

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.

11. Glenmark 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.

12. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Glenmark's financial condition as reflected in the Financial Disclosures referenced in Paragraph 4.

a. In the event that Glenmark fails to pay the Settlement Amount as provided in the payment schedule set forth in Attachment A, Glenmark shall be in Default of Glenmark's payment obligations ("Default"). The United States will provide a written Notice of Default, and Glenmark shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Glenmark, or to such other representative as Glenmark shall designate in advance in writing. If Glenmark fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, Glenmark agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement or bring any civil and/or administrative claim, action, or proceeding against Glenmark for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by Glenmark to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to Glenmark and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be

entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Glenmark agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Glenmark waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against Glenmark within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on March 23, 2020. Glenmark agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of Uncured Default, OIG-HHS may exclude Glenmark from participating in all Federal health care programs until Glenmark pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Glenmark. Glenmark waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Glenmark wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Glenmark will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

13. In exchange for valuable consideration provided in this Agreement, Glenmark acknowledges the following:

a. Glenmark has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Glenmark, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Glenmark was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of Glenmark's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Glenmark or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Glenmark's debts, or to adjudicate Glenmark as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Glenmark or for all or any substantial part of Glenmark's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Glenmark for the claims that would otherwise be covered by the releases provided in Paragraph 2 above;

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Glenmark in the amount of \$175,000,000, less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Glenmark, a receiver, trustee, custodian, or other similar official for Glenmark.

f. Glenmark agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 13.e is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Glenmark shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Glenmark waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Glenmark that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on March 23, 2020.

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

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

16. This Agreement is governed by the laws of the United States. The exclusive 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.

17. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

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

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 on Glenmark's successors, transferees, heirs, and assigns.

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

22. 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: Jacqueline C. Romero
JACQUELINE C. ROMERO
United States Attorney
Eastern District of Pennsylvania

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

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

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

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

DATED: 08/30/24

BY:

SUSAN GILLIN

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SUSAN E. GILLIN

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: _____

SUSAN E. GILLIN
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: 08/23/2024

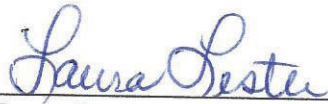
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for SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

GLENMARK PHARMACEUTICALS INC., USA

DATED: 8/23/24

BY: 
Laura Lester
Senior Vice President & General Counsel,
North America
Glenmark Pharmaceuticals Inc., USA

DATED: 8/23/2024

BY: 
David Tolley
Counsel for Glenmark Pharmaceuticals Inc., USA

ATTACHMENT A

Glenmark Pharmaceuticals Payment Schedule

Year	Payment	4.250% Interest¹	Principal	Balance
				25,000,000.00
9/16/2024	2,823,116.44	323,116.44	2,500,000.00	22,500,000.00
8/30/2025	3,411,712.33	911,712.33	2,500,000.00	20,000,000.00
8/30/2026	5,850,000.00	850,000.00	5,000,000.00	15,000,000.00
8/30/2027	5,637,500.00	637,500.00	5,000,000.00	10,000,000.00
8/30/2028	5,425,000.00	425,000.00	5,000,000.00	5,000,000.00
8/30/2029	5,212,500.00	212,500.00	5,000,000.00	-
Total	28,359,828.77	3,359,828.77	25,000,000.00	

Note:

1. The 09/16/2024 payment shown above includes handshake interest for 111 days (05/28/2024-09/16/2024).