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"), Akorn Operating Company LLC, ("Akorn") and Albermarle, LLC ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Akorn is a pharmaceutical manufacturer with a principal place of business in Lake Forest, Illinois. During the relevant period Akorn manufactured and sold brand name and generic pharmaceutical products in the United States, including 1) Diclofenac Sodium 1%, national drug code ("NDC") 50383-272-01, a generic nonsteroidal anti-inflammatory cream indicated for external use only as an arthritis pain relief ("Diclofenac"); 2) Olopatadine Hydrocholoride 0.1% and 0.2%, NDCs 17478-105-05 and 17478-305-12, a generic antihistamine eyedrop ("Olopatadine"), and 3), Azelastine Hydrochloride 0.15%, NDC 50383-942-30, a generic antihistamine nasal spray ("Azelastine").

B. The U.S Food and Drug Administration ("FDA") originally approved Diclofenac, Olopatadine, and Azelastine as generic equivalents of other drug manufacturers' brand name products. The brand name product for which each Akorn product was approved as an equivalent is referred to as the "Reference Listed Drug" ("RLD") for that Akorn product. The RLD for each Akorn product was originally approved as a "prescription use only" ("Rx-only") drug by FDA, and was still Rx-only when Akorn sought and received FDA approval for its generic Diclofenac, Olopatadine, and Azelastine products. Accordingly, the FDA approved each of Akorn's products as Rx-only as well.

C. Under certain circumstances, drug manufacturers may seek to convert an Rx-only product to "over the counter" ("OTC") status. Drug manufacturers may initiate a change in marketing status from Rx-only to OTC through a process referred to as an Rx-to-OTC switch. A "full" Rx-to-OTC switch involves converting all aspects of a product's approved application to OTC status and thus no indication, strength, route of administration, dosage form, patient population, or condition of use for that product remains approved for Rx-only use after a "full" switch. Section 503(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) does not permit both Rx-only and OTC versions of the same drug to be marketed at the same time. Thus, when an RLD undergoes a "full" switch to OTC status it is no longer an Rx-only drug under the FDCA, and generic equivalents of that RLD are not properly considered Rx-only drugs under the FDCA either. OTC drugs that are labeled Rx-only are considered misbranded under the FDCA. 21 U.S.C. § 353(b)(4)(B). Thus, when the RLD for a generic drug is approved for a full switch to OTC use, an application holder of a generic equivalent to that RLD is required either to seek FDA approval for its own product to switch to OTC status or seek to withdraw its generic's Rx-only approval and cease marketing it.

D. The FDA approved a full Rx-to-OTC switch for the RLDs of Diclofenac and Olopatadine in February 2020 and for the RLD of Azelastine in June 2021. This meant that each of these RLDs, as of its OTC switch date: (i) could be marketed by the relevant application holders for OTC use; (ii) could no longer be marketed as an Rx-only drug; and, (iii) were no longer approved to state "Rx only" on its label or packaging.

E. Medicare Part D provides coverage for "covered part D drugs," which is defined to include drugs "that may be dispensed only upon a prescription" and does not include OTC products.

F. On June 28, 2021, Relator filed a qui tam action in the United States District Court for the District of Massachusetts, captioned *United States ex rel. Albermarle, LLC v. Akorn Operating Company LLC*, No. 21-cv-11060-ADB, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). The United States intervened in part, with respect to Relator's claims as to Akorn, in the Civil Action on or about September 7, 2022.

G. The United States contends that Akorn 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").

H. Akorn 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.

I. The United States contends that it has certain civil claims against Akorn for engaging in the conduct described below, hereinafter referred to as the "Covered Conduct." Akorn admits, acknowledges, and accepts its responsibility for the following facts:

Akorn delayed seeking the required OTC conversions for Diclofenac, Olopatadine, and Azelastine, even after learning that the RLDs for each product had converted to OTC status. In particular, Akorn delayed Diclofenac, Olopatadine, and Azelastine losing their Rx-only labeling because it believed that continuing to sell each as purportedly Rx-only would be more profitable for the company. Accordingly, Akorn continued to sell newly manufactured units of Diclofenac, Olopatadine, and Azelastine under its obsolete Rx-only labeling rather than beginning the process of converting these products to OTC or withdrawing their approval and ceasing their distribution. Akorn did not apply to FDA for an OTC conversion of Diclofenac until March 2021 or for Olopatadine until January 2021. Akorn eventually sought to withdraw its FDA

approval for Azelastine, rather than convert it to OTC use, but did not do so until January 2022. FDA implemented this withdrawal in February 2022.

Akorn caused the submission of false claims to Medicare Part D by continuing to sell each product under Rx-only labeling prior to its applications for OTC conversion with respect to Diclofenac and Olopatadine, and prior to its withdrawal regarding Azelastine, because Medicare does not cover non-prescription drugs and no meaningful difference existed between these products and their now-OTC reference listed drugs.

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. Akorn shall pay to the United States $7,900,000.00 plus interest at a rate of three (3.0) percent per annum running from June 28, 2022, until the date of payment (Settlement Amount), of which $5,136,359.00 is restitution, no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay $946,887.00, plus a pro rata share of any interest included in the Settlement Amount, to Relator by electronic funds transfer (Relator's Share).

3. Upon completion of this settlement, and final dismissal of Relator's Complaint by the Court, Akorn will pay Relator's counsel $45,000 for expenses, and attorneys' fees and costs, and/or for wrongful termination claims under subsection 3730(h).

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases Akorn together with its current and former parents, divisions, subsidiaries, successors, 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; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; and the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Upon the United States' receipt of the Settlement Amount and Akorn's full payment of the amount due under Paragraph 3, Relator, for itself and for its affiliates and their respective heirs, successors, attorneys, agents, and assigns, fully and finally releases Akorn and its affiliates and their respective current and former parents, divisions, subsidiaries, successors, assigns, affiliates, directors, officers, and employees from (1) any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Relator has asserted, could have asserted, or may assert in the future against Akorn related to the Covered Conduct and Relator's investigation and prosecution thereof; and (2) any liability to Relator or its affiliates and their respective heirs, successors, attorneys, agents, and assigns arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

6. Notwithstanding the releases given in Paragraph 4 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 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.

7. Relator and its affiliates and their respective 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 Relator's Share, Relator and its affiliates and their respective 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.

8. Akorn waives and shall not assert any defenses Akorn 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.

9. Akorn 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 Akorn 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.

10. Akorn fully and finally releases Relator, its affiliates, and their respective current and former parents, divisions, subsidiaries, successors, assigns, affiliates, managers, members, directors, officers, and employees from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Akorn has asserted, could have asserted, or may assert in the future against Relator, related to the Covered Conduct and Relator's investigation and prosecution thereof.

11. 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 Akorn agrees not to resubmit to any Medicare 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.

12. Akorn 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 Akorn, 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) Akorn'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 attorneys' fees);

(4) the negotiation and performance of this Agreement; and

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

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

13. Akorn agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Akorn 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. Akorn 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. In exchange for valuable consideration provided in this Agreement, Akorn and Relator acknowledge the following:

a. Akorn 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 Akorn, 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 Akorn 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 Akorn'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, Akorn 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 Akorn's debts, or to adjudicate Akorn as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Akorn or for all or any substantial part of Akorn'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 Akorn for the claims that would otherwise be covered by the releases provided in Paragraph 4 above;

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Akorn in the amount of $72 million, 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 a receiver, trustee, creditor, custodian, or similar official;

(iii) if any payments are avoided and recovered by a receiver, trustee, creditor, custodian, or similar official**,** the United States shall not be responsible for the return of any amounts already paid by the United States to Relator; and

(iv) if, notwithstanding subparagraph (iii), any amounts already paid by the United States to Relator pursuant to Paragraph 2 are recovered from the United States in an action or proceeding filed by a receiver, trustee, creditor, custodian, or similar official in or in connection with a bankruptcy case that is filed within two years of the Effective Date of this Agreement or of any payment made under Paragraph 1 of this Agreement, Relator shall, within thirty days of written notice from the United States to the undersigned Relator's counsel, return to the United States all amounts recovered from the United States.

f. Akorn agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 15.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. Akorn 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). Akorn 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 Akorn that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on June 28, 2021.

15. 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 4, 5, and 16 (waiver for beneficiaries paragraph).

16. Akorn 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.

17. 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 as to claims against Akorn, pursuant to Rule 41(a)(1) and the terms of this Settlement Agreement.

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

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

20. 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.

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

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

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

24. This Agreement is binding on Akorn's successors, transferees, heirs, and assigns.

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

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

27. 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: 9/9/2022 BY: _____

Augustine M. Ripa
Senior Counsel for Health Care fraud
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/9/2022 BY: _____

Abraham R. George
Assistant United States Attorney
Chief, Affirmative Civil Enforcement
District of Massachusetts

DATED: 9/08/2022 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

DEFENDANT – Akorn

DATED: 09/06/2022 | 16:24:59 PDT BY: DocuSigned by: C0176128AA714C5...

Douglas Boothe
President and Chief Executive Officer
Akorn Operating Company LLC

DATED: 9/7/22 BY:

D. Jacques Smith
Partner
ArentFox Schiff LLP
Counsel for Akorn Operating Company LLC

Albermarle, LLC - RELATOR

DATED: 9/7/22 BY: _____
David Lubitz, Manager
Albermarle, LLC

DATED: 9/7/22 BY: _____
Gregg Shapiro
Newman & Shapiro
Counsel for Albermarle, LLC