

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice (the “United States”); kaléo, Inc. (“kaléo” or “Kaléo”); and Rebecca Socol (the “Relator”), through their authorized representatives (together, the “Parties”).

RECITALS

A. Kaléo is a Virginia corporation with headquarters in Richmond, Virginia. Kaléo is a pharmaceutical manufacturer.

B. From October 2016 to September 2020, Kaléo manufactured and marketed Evzio, the brand name for its injectable form of naloxone hydrochloride. Evzio was one of several commercially available naloxone products indicated for use on an emergent basis in the case of opioid overdose. During the relevant period, Evzio was the highest-priced version of naloxone on the market, and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio.

C. On January 10, 2018, Relator filed an action in the United States District Court for the District of Massachusetts with docket number 18-cv-10050-RGS, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator filed an amended complaint on August 8, 2018. The Civil Action alleges, among other things, that kaléo submitted or caused the submission of false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”), for Evzio, by engaging in a scheme whereby materially false statements and documents were used to obtain favorable prior authorization determinations for Evzio, by procuring medically unnecessary Evzio prescriptions, and by submitting or causing the submission of claims that were tainted by violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

D. The United States contends that kaléo caused Evzio claims for payment to be submitted to Medicare, the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”), and the Federal Employees Health Benefits Program (“FEHBP”), 5 U.S.C. §§ 8901-8914.

E. The United States contends that, between March 14, 2017 and April 30, 2020, kaléo directed Evzio prescriptions to specialty pharmacies that submitted false claims for Evzio prescriptions to Medicare, TRICARE, and the FEHBP in violation of the False Claims Act, 31 U.S.C. § 3729 and the common law. In particular, the United States contends:

- i. Kaléo encouraged or directed doctors who prescribed Evzio to send Evzio prescriptions to preferred pharmacies that were perceived to be successful in obtaining insurance coverage for the drug. Among such preferred Evzio pharmacies and pharmacy chains were Royal Care Pharmacy in Virginia (“Royal Care”); Benzer Pharmacy Holding, LLC in Florida and its affiliated pharmacies (collectively “Benzer”); Plymouth Towne Care Pharmacy, Inc. d/b/a People’s Drug Store in Indiana (“People’s”); and Shaska Pharmacy LLC d/b/a Ray’s Drugs in Michigan (“Ray’s Drugs”).
- ii. Kaléo sought out and cultivated business relationships with specialty pharmacies that were willing to assist with Evzio prior authorization requests, including Royal Care, Benzer, People’s, and Ray’s Drugs.
- iii. Royal Care, Benzer, People’s, and Ray’s Drugs submitted Evzio prior authorization requests to Medicare, TRICARE, and the FEHBP that were false because (a) the pharmacies misrepresented to insurers that it was the prescribing physicians who were submitting the prior authorization requests when the pharmacies themselves did so; and/or (b) the prior authorization forms contained false or misleading assertions about

patients' medical histories, such as false statements that patients had previously tried and failed less costly alternatives to Evzio.

- iv. Kaléo knew of or deliberately ignored information about improper prior authorization practices at Royal Care, Benzer, People's, and Ray's Drugs. Nonetheless, kaléo took no steps to terminate its business relationship with those pharmacies on account of these practices.
- v. In addition, kaléo knew, or disregarded information indicating, that specialty pharmacies at times dispensed Evzio without collecting or attempting to collect co-payment obligations from Medicare or other government health program beneficiaries, and without taking steps to confirm whether such beneficiaries suffered from a financial hardship that could have affected their ability to pay for their Evzio co-payment.
- vi. In addition, kaléo provided illegal remuneration to prescribing physicians and their office staff in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), to induce and reward their prescribing of Evzio. Specifically, Evzio sales representatives provided doctor's offices with deliveries of food and beverages, as well as occasional holiday gifts, even when there was no connection to any educational or other business event.
- vii. Kaléo knew or deliberately ignored that Royal Care submitted false claims for payment to Medicare, TRICARE, and the FEHBP for Evzio prescriptions during the period March 14, 2017 through April 30, 2020.
- viii. Kaléo knew or deliberately ignored that People's and Ray's Drugs submitted false claims for payment to Medicare, TRICARE, and the

FEHBP for Evzio prescriptions during the period August 8, 2017 through April 30, 2020.

- ix. Kaléo obtained unjust enrichment for Evzio sales based on Benzer's submitting false claims for payment to Medicare, TRICARE, and the FEHBP during the period December 8, 2017 through April 30, 2020.

The conduct described in this Paragraph E shall hereinafter be referred to as the "Covered Conduct."

F. 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. Relator and kaléo have entered into a separate settlement agreement relative to Relator's claim for 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. Kaléo shall pay to the United States \$12,743,000, plus interest accruing at an annual rate of 1.5% per annum from June 24, 2021, and continuing until and including the day of payment (the "Settlement Amount"). Kaléo shall pay the Settlement Amount 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. Of the Settlement Amount, \$7,309,385 is restitution to the United States.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay the Relator by electronic funds transfer 20% of the Settlement Amount ("Relator's Share").

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount under Paragraph 1, the United States releases kaléo from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 5 below, and upon the United States' receipt of the Settlement Amount due under Paragraph 1, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns (collectively "Releasers"), releases kaléo and its current and former parent corporations or entities, partnerships, joint ventures, limited liability company owners, direct and indirect subsidiaries, brother or sister corporations, divisions, affiliates, current or former corporate owners, and the corporate successors and assigns of any of them, and their current and former officers, directors, employees, and agents, individually and collectively (collectively "Releasees"), from any and all claims Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-33 from the beginning of time through the Effective Date of this Agreement.

5. Notwithstanding the releases given in Paragraphs 3 and 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.

6. Relator and her 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 Relator's Share, Relator and her 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.

7. Kaléo waives and shall not assert any defenses kaléo 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.

8. Kaléo fully and finally release the United States, its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that kaléo 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.

9. Kaléo fully and finally releases the Relator from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that kaléo has asserted, could have asserted, or may assert in the future against the Relator related to the Civil Action and the Relator's investigation and prosecution thereof.

10. 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 kaléo agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

11. Kaléo 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 kaléo, 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 and criminal investigation(s) of the matters covered by this Agreement;

- (3) kaléo's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal 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 kaléo makes to the United States pursuant to this Agreement and any payments that kaléo 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 kaléo, and kaléo 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 kaléo or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

12. Kaléo agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, kaléo shall encourage, and agree 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. Kaléo 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 kaléo's behalf.

13. 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 14 (waiver for beneficiaries paragraph), below.

14. Kaléo 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.

15. Upon receipt of the settlement payment described in Paragraph 1, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action as to kaléo pursuant to Rule 41(a)(1). The dismissal shall be with prejudice to the United States and the Relator as to the Covered Conduct, and with prejudice to the Relator and without prejudice to the United States as to all other claims against kaléo.

16. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, with the exception of the Relator's right to attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d).

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

18. 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.

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

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

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

22. This Agreement is binding on kaléo's successors, transferees, heirs, and assigns.


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

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

25. 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: 11/9/2021

BY: 
DAVID J. DERUSHA
ABRAHAM R. GEORGE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: _____

BY: **SARAH ARNI** Digitally signed by SARAH ARNI
Date: 2021.11.09 08:14:07 -05'00'
SARAH M. ARNI
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

KALEO, INC.

DATED: 11/5/21

BY: 

JAY MOORE
General Counsel
Kaleo, Inc.

DATED: 11/5/21

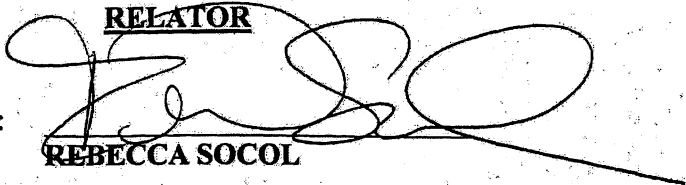
BY: 

JONATHAN M. PHILLIPS
Gibson, Dunn & Crutcher LLP
Counsel for Kaleo, Inc.

RELATOR

DATED: 11/08/21

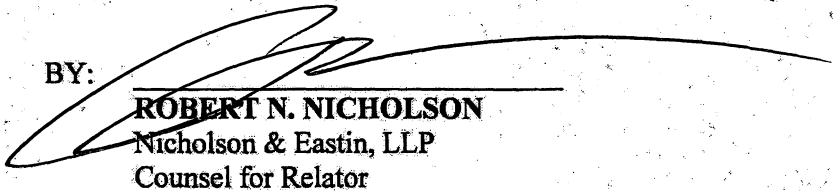
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REBECCA SOCOL

DATED: 11/8/21

BY:



ROBERT N. NICHOLSON
Nicholson & Eastin, LLP
Counsel for Relator