

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 United States Customs & Border Patrol (“CBP”) of the Department of Homeland Security (collectively the “United States”), Danco Laboratories, LLC (“Danco”), and Life Legal Defense Foundation (“Relator”) (collectively the “Parties”), through their authorized representatives.

RECITALS

A. Danco is a U.S. pharmaceutical company and is in the business of distributing a single pharmaceutical product—Mifeprex—within the United States. Between January 1, 2010 and December 31, 2019, (the “Relevant Period”), Danco manufactured Mifeprex for a period of time in the United States and for a period of time in the European Union. During the Relevant Period, Danco imported the active pharmaceutical ingredient for Mifeprex (mifepristone) from outside the United States into the United States.

B. On January 29, 2021, Relator filed a *qui tam* action under seal in the United States District Court for the Eastern District of Texas captioned *United States ex rel. Life Legal Defense Foundation v. Danco Laboratories, LLC, et al.*, Case No. 21-cv-0088, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The *qui tam* complaint alleged, among other things, that Danco failed to label its imported pharmaceutical product with the country of origin, and should have paid “marking duties” as a consequence of these labeling violations. The *qui tam*

complaint did not allege that any of Danco’s pharmaceutical products are defective, unsafe, ineffective, or otherwise violate FDA regulations.

C. The Tariff Act of 1930 and its implementing regulations require “every article of foreign origin...be marked...to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article.” 19 U.S.C. § 1304(a); 19 C.F.R. § 134.1. When an individual or entity fails to properly mark the country of origin, the individual or entity is required to export, destroy, or pay duties for the unmarked articles. 19 U.S.C. § 1304(i); 19 C.F.R. § 134.2.

D. The United States contends that between January 1, 2010 through December 31, 2019, Danco did not mark its pharmaceutical product (Mifeprex) with the country of origin or pay marking duties for these unmarked products, including marking duties for the value of all “assists,” as defined by 19 U.S.C. § 1401a(b)(1)(C), before distributing them to consumers within the United States. As a consequence of these actions, the United States contends that Danco “knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] an obligation to pay or transmit money or property to the Government...” in violation of the False Claims Act. 31 U.S.C. 3729(a)(1)(G). The conduct described in this Paragraph is referred to below as the “Covered Conduct.”

E. This Settlement Agreement is neither an admission of liability by Danco nor a concession by the United States that its claims are not well founded.

F. Danco denies the United States’ allegations in Paragraph D and the Relator’s allegations in the Civil Action.

G. 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.

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. Danco shall pay to the United States \$765,000 ("Settlement Amount"), of which \$382,000 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Eastern District of Texas. Danco shall pay to the United States the Settlement Amount plus interest accrued at the rate of 3.625% per annum, in accordance with the payment schedule attached hereto as Exhibit A. On or before April 24, 2023, Danco shall pay the United States the initial fixed payment in the amount of \$255,000 and thereafter make principal payments with interest according to the schedule in Exhibit A. The entire balance of the Settlement Amount, or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

2. In the event that Danco fails to pay the Settlement Amount as provided in the payment schedule set forth in Exhibit A, Danco shall be in Default of Danco's payment obligations ("Default"). The United States will provide a written Notice of Default, and Danco 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 Danco, or to such other representative as Danco shall designate in advance in writing. If Danco 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 (consisting of the outstanding principal and the interest accrued at 3.625% as of the date of Default) shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 8% per annum, compounded daily from the date of Default.

3. In the event of Uncured Default, Danco agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Danco for the claims that would otherwise be covered by the releases provided in Paragraph 6, with any recovery reduced by the amount of any payments previously made by Danco to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Danco 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, Danco 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, Danco 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 Danco 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 the Effective Date of the Agreement. Danco 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.

4. Conditioned upon the United States receiving the initial fixed payment in the amount of \$255,000 from Danco, as described in Paragraph 1 above, and as soon as feasible after receipt, the United States shall pay \$38,250.00 to Relator by electronic funds transfer. Contingent upon the United States receiving each additional payment from Danco identified in Exhibit A, as soon as feasible after receipt of each payment, the United States agrees to make the corresponding additional payment to Relator according to the schedule in Exhibit A.

5. No later than twenty (20) days after the Effective Date of this Agreement, Danco shall pay relator \$46,220.28 for expenses, attorneys' fees, and costs, in accordance with 31 U.S.C. § 3730(d)(2).

6. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases Danco, together with its current and former parent entities; direct and indirect subsidiary entities; brother and sister entities; owners; affiliates; and the successors and assigns of any of them (the "Danco Released Parties") 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 Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

7. Conditioned upon the United States' receipt of the Settlement Amount, and the amount for expenses, attorneys' fees and costs to be remitted to Relator pursuant to 31 U.S.C. § 3730(d), as described in Paragraph 5, Relator, for itself and for its heirs, successors, attorneys, agents, and assigns, fully and finally releases, waives, and forever discharges, and will be deemed to have released and forever discharged the Danco Released Parties, as well as Danco's officers and directors; agents, servants, and employees and the assigns of each of them; and the successors and assigns of any of them from any civil monetary claim the Relator has or may have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, including § 3730(b) and (d) or any similar federal or state statute, and from any and all liability, claims, demands, actions, rights, suits, debts, obligations, losses, damages (including treble damages and any civil penalties), punitive damages, costs, expenses, or causes of action of any kind, character, or nature whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statutes or

regulations, or in common law or otherwise, that Relator, its heirs, successors, attorneys, agents, and assigns otherwise would have standing to bring as of the date of this Agreement arising in any way out of, relating in any way to, or connected in any way to the claims Relator asserted or could have asserted in the Civil Action, and the facts, claims, and circumstances alleged in, arising under, arising from, or relating to the filing of the Civil Action.

8. Notwithstanding the releases given in Paragraph 6 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 the Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability 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.

9. Relator and its 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 its 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.

10. Danco waives and shall not assert any defenses Danco 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.

11. Danco 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 Danco 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.

12. Danco fully and finally releases the Relator together with its current and former parent entities; direct and indirect subsidiary entities; brother and sister entities; current or former owners; officers, directors, and affiliates; agents, servants, and employees and the assigns of each of them; and the successors and assigns of any of them (the “Relator Released Parties”) from any claims (including attorneys’ fees, costs, and expenses of every kind and however denominated) that Danco has asserted, could have asserted, or may assert in the future against the Relator Released Parties related to the Civil Action and Relator’s investigation and prosecution thereof.

13. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of Danco, and 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) Danco’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;
- (5) the payment Danco makes to the United States pursuant to this Agreement and any payments that Danco may make to Relator, including costs and attorneys’ fees,

are unallowable costs for government contracting purposes (hereinafter referred to as “Unallowable Costs”).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Danco, and Danco shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, Danco shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Danco or any of its subsidiaries or affiliates from the United States. Danco agrees that the United States, at a minimum, shall be entitled to recoup from Danco any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Danco’s books and records and to disagree with any calculations submitted by Danco or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Danco, or the effect of any such Unallowable Costs on the amount of such payments.

14. This Agreement is intended to be for the benefit of the Parties only.

15. On or after the Effective Date of this Agreement, the United States will file a notice of intervention in the Civil Action with regard to the Covered Conduct, and, upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Notice of Dismissal of the

Civil Action pursuant to Rule 41(a)(1). The dismissal shall be with prejudice to Relator, and without prejudice to the United States except as to the Covered Conduct.

16. Except as provided in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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 Eastern District of Texas. 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 Danco'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 of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[signatures follow]


THE UNITED STATES OF AMERICA

DATED: March 29, 2023

BY: 

DANIEL W. KASTNER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice


DATED: March 29, 2023

BY: 

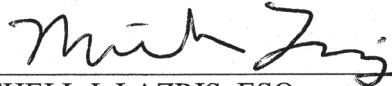
JAMES GILLINGHAM
ADRIAN GARCIA
Assistant United States Attorneys
United States Attorney's Office for the
Eastern District of Texas

DANCO LABORATORIES, LLC - DEFENDANT


DATED: 3/28/2023

BY: 
W. BRADLEY DANIEL
Danco Laboratories, LLC

DATED: 3/28/2023


BY: 
MITCHELL J. LAZRIS, ESQ.
Counsel for Danco Laboratories, LLC

DATED: 3/28/2023

BY: 
CHRISTOPHER L. PEELE, ESQ.
Counsel for Danco Laboratories, LLC

LIFE LEGAL DEFENSE FOUNDATION - RELATOR

DATED: 3.28.23

BY: 
ALEXANDRA SNYDER
Chief Executive Officer

DATED: 3/28/23

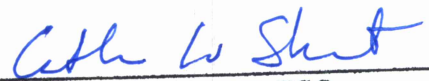
BY: 
CATHERINE W. SHORT, ESQ.
Vice President Legal Affairs

EXHIBIT A

PAYMENT SCHEDULE

Payment Date	Payment	Interest (3.625%)	Principal	Balance	Relator Share
4/24/2023	\$255,000.00		\$255,000.00	\$510,000.00	\$38,250.00
7/24/2023	\$174,609.21	\$4,609.21	\$170,000.00	\$340,000.00	\$26,191.38
10/24/2023	\$173,106.58	\$3,106.58	\$170,000.00	\$170,000.00	\$25,965.98
1/24/2024	\$171,553.29	\$1,553.29	\$170,000.00	\$0.00	\$25,732.99
Total	\$774,269.08	\$9,269.08	\$765,000.00		\$116,140.35