

## 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”), and DJ Drugs & Surgicals Inc. (“DJ Drugs”) (hereafter collectively referred to as the “Parties”), through their authorized representatives.

### RECITALS

A. DJ Drugs is a specialty pharmacy incorporated in New York and which operates currently in New York City.

B. Proprotein convertase subtilisin kexin type 9 (“PCSK9”) inhibitors are a class of cholesterol-lowering medication. During the relevant period, PCSK9 inhibitors were more expensive than many other cholesterol-lowering medications, and insurers frequently required the submission of prior authorization requests before they would approve coverage for PCSK9 inhibitors.

C. The United States contends that DJ Drugs 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”).

D. DJ Drugs admits, acknowledges, and accepts its responsibility for the following facts. DJ Drugs processes and fills prescriptions for PCSK9 inhibitors, and often completed and submitted prior authorization requests for those prescriptions. Between June 2017 and October 2018, on at least twenty-eight occasions, and without express authorization from the prescribing physician, DJ Drugs removed certain information in supporting documentation (e.g., laboratory results, patient medical records) associated with PCSK9 prior authorization requests and then submitted the altered documents to Medicare plan sponsors for approval. The conduct described in this paragraph is referred to below as the “Covered Conduct.”

E. The United States contends that it has certain civil claims against DJ Drugs arising from the covered conduct during the period from June 2017 through October 2018.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. DJ Drugs shall pay to the United States \$115,000 plus interest accruing at an annual rate of 3.0% from May 4, 2022 (“Settlement Amount”). No later than 10 days after the Effective Date of this Agreement, DJ Drugs shall make an initial payment to the United States of \$23,000. Thereafter, DJ Drugs shall pay the United States the remaining balance, plus accrued interest on the outstanding balance, in 4 payments in 90-day intervals after the Effective Date, the last and remaining payment to be due no later than 360 days after the Effective Date of the settlement. DJ Drugs shall make all such payments to the United States by electronic funds transfers pursuant to written instructions provided by the United States Attorney’s Office for the District of Massachusetts. The entire balance of the Settlement Amount or any portion thereof may be prepaid at any time without penalty. Of the Settlement Amount, all is restitution to the United States. If DJ Drugs is sold, merged, or transferred, or all or substantially all of DJ Drugs’ assets are sold, merged, or transferred into another non-affiliated entity, DJ Drugs shall promptly notify the United States, and all remaining payments owed pursuant to the Settlement Agreement shall be accelerated and become immediately due and payable upon consummation of such.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases DJ Drugs, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns (the “DJ Drugs Releasees”), from any civil or

administrative monetary claim the United States has for the Covered Conduct under the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release 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 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;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

4. DJ Drugs waives and shall not assert any defenses DJ Drugs 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.

5. DJ Drugs fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that DJ Drugs has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. 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 DJ Drugs 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.

7. DJ Drugs 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 DJ Drugs, 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, and criminal investigation of the matters covered by this Agreement;

- (3) DJ Drugs' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation, and criminal investigation of the matters covered by this Agreement (including attorneys' fees); and
- (4) the negotiation and performance of this Agreement;
- (5) the payment DJ Drugs 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 DJ Drugs, and DJ Drugs 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 DJ Drugs or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

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

9. 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 10 (waiver for beneficiaries paragraph), below.

10. DJ Drugs 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.

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

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

13. 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 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.

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

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


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

17. This Agreement is binding on DJ Drugs' successors, transferees, heirs, and assigns.

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


19. 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:  Digitally signed by CHARLES WEINOGRAD  
Date: 2022.07.26 13:52:19 -04'00'

Charles B. Weinograd  
Assistant United States Attorney  
United States Attorney's Office for the  
District of Massachusetts

DJ DRUGS & SURGICALS INC.

DATED: 7/26/22 BY: 

John Lee  
Owner and Chief Executive Officer

DATED: 07.26.2022 BY: 

Eric J. Bach  
Marina Plotkin  
Counsel for DJ Drugs & Surgicals Inc.