

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”), the Defense Health Agency (“DHA”), acting on behalf of the TRICARE Program, and the United States Department of Veterans Affairs (collectively, the “United States”), ASD Specialty Healthcare, LLC, and Julianne Nunnelly and Matthew Shanks (collectively, the “Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Cencora, Inc. (“Cencora”), a publicly traded pharmaceutical wholesale company, distributes specialty pharmaceutical products through its subsidiary, ASD Specialty Healthcare LLC, d/b/a Besse Medical (“ASD” or “Besse”). ASD’s headquarters are located in Carrollton, Texas, and it distributes pharmaceutical products, including ophthalmological injections, to physicians and medical practices across the United States.

B. On July 28, 2020, Julianne Nunnelly and Matthew Shanks filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Does 1-3 v. Regeneron Pharmaceuticals, Inc., Besse Medical, et al.*, No. 20-cv-11401-PBS (D. Mass.), 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 in the Civil Action on November 27, 2023.

C. The United States contends that ASD 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 TRICARE Program, 10 U.S.C. §§ 1071-1110b

(“TRICARE”); and to the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17.

D. ASD admits, acknowledges, and accepts responsibility for the following facts:

- On May 31, 2017, ASD acquired the rights to PODIS, an inventory management system specialized for retina practices to manage inventory of and reimbursements for high-cost injectable medications, such as drugs that treat wet age-related macular degeneration (“wet AMD”).
- Prior to the ASD acquisition, the company that owned PODIS charged monthly license fees to retina practices to use PODIS. Following the ASD acquisition, and through November 30, 2023, ASD made PODIS available at no monetary cost to the ASD customers set forth in a separate letter dated December 12, 2024, which is incorporated herein by reference (the “Practice List”).
- During that time, ASD provided PODIS at no monetary cost to customers on the Practice List on the condition they enter into “prime vendor agreements” or “PVAs” that required them to purchase a certain percentage of their specialty drugs from ASD. The PVAs stated that ASD provided PODIS at no monetary cost in exchange for certain data rights.
- ASD did not provide PODIS at no monetary cost to customers that did not enter into PVAs with ASD. Instead, ASD required those customers to pay a monthly fee for access to PODIS. Following its acquisition of PODIS, ASD discontinued access to PODIS for non-ASD customer retina practices which had used PODIS prior to the acquisition, including customers who offered to pay a monthly fee to continue using PODIS.

This conduct is referred to below as the “Covered Conduct.”

E. The United States contends that it has certain civil claims against Defendants for submitting or causing the submission of false claims for payment to Federal Health Care Programs that were tainted by violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arising from the Covered Conduct. More specifically, the United States contends that ASD knowingly and willfully paid remuneration to the practices on the Practice List to induce them to order drugs from ASD.

F. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' 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. ASD shall pay to the United States one million, six hundred and seventy-one thousand, three hundred and sixty-eight dollars (\$1,671,368) (Settlement Amount), and interest on the Settlement Amount at a rate of 4.375% per annum from July 2, 2024, of which eight hundred and thirty-five thousand, six hundred and eighty four dollars (\$835,684) is restitution, no later than seven (7) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount and applicable interest and as soon as feasible after receipt, the United States shall pay Relator a lump sum of two-hundred fifty-thousand, seven-hundred and five dollars and twenty cents (\$250,705.20) plus fifteen percent (15%) of the interest received pursuant to Paragraph 1 (Relators' Share) by electronic funds transfer.

3. ASD shall pay to Relators \$250,000.00 to fully and finally resolve Relators' claim for expenses, attorneys' fees and costs (the "Fee Settlement Amount"), as soon as feasible after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions from Relators' counsel.

4. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases ASD, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; any other subsidiaries or subdivisions of Cencora; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, 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.

5. Subject to the exceptions in Paragraph 8 below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Cencora, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; any other subsidiaries or subdivisions of Cencora; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, from any and all actions, causes of action, debts, dues, claims and demands of every name and nature, without limitation at law, in equity, or as to administrative relief, which Relators and/or Relators' counsel may have had, now have, or may have, whether known or unknown, by reason of any matter or thing arising from the beginning of time through the Effective Date, and from any civil monetary

claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

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

7. Relators and their 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 Relators' receipt of the Relators' Share, Relators and their 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. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release Cencora, together with its current and former officers, agents, and employees; current and former parent corporations; direct and indirect subsidiaries, divisions, or subdivisions; brother or sister corporations; current or former corporate owners; and the corporate successors and assigns of any of them, from any liability to Relators arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

9. ASD waives and shall not assert any defenses ASD 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.

10. ASD 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 ASD 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 Civil Action, Covered Conduct, or the United States' investigation or prosecution thereof.

11. ASD fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that ASD has asserted, could

have asserted, or may assert in the future against the Relators, related to the Civil Action and the Relators' investigation and prosecution thereof.

12. 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), TRICARE, the Department of Veterans Affairs, or any state payer, related to the Covered Conduct; and ASD agrees not to resubmit to any Medicare contractor, TRICARE, the Department of Veterans Affairs, 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.

13. ASD 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 ASD, 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) ASD'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 ASD makes to the United States pursuant to this Agreement and any payments that ASD may make to Relators, 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 ASD, and ASD 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 ASD or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

14. ASD agrees to cooperate fully and truthfully with the United States' investigation of the Civil Action as to unaffiliated individuals and entities not released in this Agreement. Upon reasonable notice, ASD agrees to make available and not impair the cooperation of its directors, officers, and employees, and shall use reasonable efforts to make available its former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of ASD and such individuals. Besse further agrees to authenticate and certify documents and data in connection with any non-privileged records produced in response to a subpoena from the United States in connection with the Civil Action.

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 16 (waiver for beneficiaries paragraph), below.

16. ASD 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 Cencora-related entities pursuant to Rule 41(a)(1). With respect to the United States, the dismissal shall be with prejudice as to the Covered Conduct. Relators' dismissal shall be with prejudice as to the Covered Conduct and all other conduct or causes of action concerning ASD, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; any other subsidiaries or subdivisions of Cencora; divisions; current or former corporate owners; and the corporate successors and assigns of any of them.

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 ASD's successors, transferees, heirs, and assigns.

25. This Agreement is binding on Relators' 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: 12/13/2024

BY: DOUGLAS ROSENTHAL Digitally signed by DOUGLAS ROSENTHAL
Date: 2024.12.13 10:15:43 -05'00'

DOUGLAS ROSENTHAL
SAMUEL LEHMAN
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 12/13/24

BY: LINDSEY ROSS Digitally signed by LINDSEY ROSS
Date: 2024.12.13 11:05:47 -05'00'

LINDSEY ROSS
DIANE SEOL
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 12/12/24

BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN
Date: 2024.12.12 19:18:55 -05'00'

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

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
DOUGLAS ROSENTHAL
SAMUEL LEHMAN
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
LINDSEY ROSS
DIANE SEOL
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

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

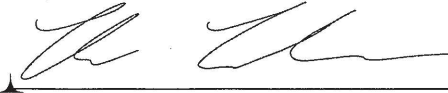
DATED: 12/12/2024

BY: _____
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AS.1099873821 Digitally signed by BLEY.PAUL.NICHOLAS.1099873821
Date: 2024.12.12 16:41:25 -0500
SALVATORE M. MAIDA
for General Counsel
Defense Health Agency
United States Department of Defense

ASD

DATED: 12/13/2024

BY:



CHRISTOPHER J. CASALENUOVO
Cencora
Vice President & Associate General Counsel


DATED: 12/13/2024

BY:




PETER K. LEVITT
MICHELLE R. PASCUCCI
Donnelly, Conroy & Gelhaar, LLP
Counsel for ASD

RELATORS

DATED: 12/12/24 BY: 
JULIANNE NUNNELLY

DATED: _____ BY: _____
MATTHEW SHANKS

DATED: 12/12/24 BY: 
ROSS BROOKS
Brooks LLC
Counsel for Relators

RELATORS

DATED: _____

BY: _____
JULIANNE NUNNELLY

DATED: 12/12/2024

BY: 
MATTHEW SHANKS

DATED: _____

BY: _____
ROSS BROOKS
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Counsel for Relators