

## SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice, United States Attorney's Office for the District of New Jersey and on behalf of the Department of Defense (collectively the "United States") and Novo Nordisk Inc. ("NNI") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

### RECITALS

A. NNI is a United States subsidiary of Novo Nordisk A/S, a global healthcare company with its United States headquarters based in New Jersey.

B. The United States contends that it has certain civil claims under the False Claims Act, 31 U.S.C. § 3729, et seq., and under the common law, against NNI arising from Department of Veterans' Affairs Federal Supply Schedule ("FSS") contracts awarded to NNI to provide medical devices to various government agencies in the United States. Specifically, the United States contends that NNI made false claims to the United States by selling to various government agencies needles that were manufactured in a non-designated country in violation of the Trade Agreements Act of 1979, 19 U.S.C. § 2501, et seq. ("TAA"). The United States asserts that in, about or between July 2012 and March 15, 2019, NNI sold to United States government agencies, either directly or through wholesalers, its NovoFine 30G 8 mm needles (NDC# 00169-1852-50) and in, about or between May 2016 and November 15, 2020, NNI sold to United States government agencies, either directly or through wholesalers, its NovoFine 32G 6mm needles (NDC# 00169-1851-89) (collectively, the "Needles") under United States Department of Veterans' Affairs Federal Supply Schedule ("FSS") Contract Nos. V797P-2204D and 36F79719D0181, and that the Needles sold to the United States government

agencies were sold in violation of the TAA, because they were manufactured in a country that is not TAA compliant. That conduct is referred to below as the "Covered Conduct".

C. NNI neither admits nor denies liability for the Covered Conduct. This Agreement is not a concession by the United States that its claims are not well-founded. NNI agrees not to make or permit to be made any public statement denying, directly or indirectly, any of the Covered Conduct or creating the impression that the Covered Conduct is without factual basis.

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. NNI shall pay to the United States the sum of Six Million, Three Hundred Thousand dollars (\$6,300,000.00) ("Settlement Amount"), of which Four Million, Two Hundred Thousand dollars (\$4,200,000.00) is restitution, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of New Jersey no later than 30 days after the Effective Date (as described below) of this Agreement.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below and conditioned upon the United States' receipt of the Settlement Amount, the United States releases NNI, its parents and subsidiaries, 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 (including claims for attorneys' fees, costs, and expenses of every kind and however denominated).

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, 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;  
and
- f. Any liability of individuals;

4. NNI waives and shall not assert any defenses NNI 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. NNI 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 NNI 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 and the United States' investigation and prosecution thereof.

6. 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 NNI, and its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit and civil and criminal investigations of the matters covered by this Agreement;
- (3) NNI's investigation, defense, and corrective actions undertaken in response to the United States' audit and civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement and any related plea agreements;
- (5) the payment NNI makes to the United States pursuant to this Agreement,

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 NNI, and NNI 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, NNI shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by NNI or any of its subsidiaries or affiliates from the United States. NNI agrees that the United States, at a minimum, shall be entitled to recoup from NNI 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 NNI's books and records and to disagree with any calculations submitted by NNI or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by NNI, or the effect of any such Unallowable Costs on the amount of such payments.

7. This Agreement is intended to be solely for the benefit of the Parties and those individuals and/or entities identify in the releases contained in paragraphs 2 and 5 of this Agreement.

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

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

10. 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 New Jersey. 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.

11. This Agreement constitutes the complete agreement between the Parties.

This Agreement may not be amended except by written consent of the Parties.

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

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

14. This Agreement is binding on NNI's successors, transferees, heirs, and assigns.

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

16. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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**SIGNATURE PAGE**

For the United States of America:



By: MARK C. ORŁOWSKI  
Assistant U.S. Attorney  
U.S. Attorney's Office  
District of New Jersey  
Civil Division  
970 Broad Street, Suite 700  
Newark, New Jersey 07102

Dated: 8/30/2022

For Novo Nordisk Inc.



CRAIG MARGOLIS, ESQ.  
Arnold & Porter  
601 Massachusetts Avenue, NW  
Washington, D.C. 20001

Dated: 8/30/22



FARRUQ JAFERY  
Vice President  
Pricing, Contract Operations & Reimbursement  
Novo Nordisk Inc.

Dated: 8/30/22