JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

April 13, 2021

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Representative James Boles, Jr.
Representative Allen McNeill
Representative Carson Smith
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Novo Nordisk

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than $75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A settlement has been executed between Novo Nordisk and the State of North Carolina.

The settlement resolves allegations that from January 1, 2010 through December 31, 2014, Novo Nordisk off-label marketed its drug Victoza.

Under the terms of North Carolina's settlement, the State of North Carolina will recover $302,206.30. Of that amount the federal government will receive $204,978.82 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive $17,674.71 of North Carolina's recovery. The North Carolina Medicaid Program will receive $32,801.18 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of $44,071.97 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive $2,679.62 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Seth Dearmin
Chief of Staff

SD:ng

cc: William Childs, NCGA Fiscal Research Division
Mark White, NCGA Fiscal Research Division
Morgan Weiss, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Novo Nordisk Inc. ("Novo Nordisk"), hereinafter collectively referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Novo Nordisk is a U.S. company and a subsidiary of Novo Nordisk U.S. Holdings, Inc., which in turn is a subsidiary of Novo Nordisk A/S. Novo Nordisk's headquarters are in Plainsboro, New Jersey. At all relevant times, Novo Nordisk distributed, sold, and marketed pharmaceutical products throughout the United States, including the drug liraglutide with the trade name Victoza® ("Victoza").

B. The Food and Drug Administration ("FDA") approved a new drug application ("NDA") for the injectable drug Victoza on January 25, 2010, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

C. At the time of approval and at all times since, Victoza's FDA-approved labeling has contained a boxed warning about the unknown risk of medullary thyroid carcinoma ("MTC") in humans, based on the fact that some rodents exposed to Victoza developed thyroid C-cell tumors (MTC is a form of thyroid tumor) during premarket testing of the drug. Because the relevance to humans of the premarket rodent findings could not be determined, the boxed warning states that it "is unknown whether Victoza

causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be determined by clinical or nonclinical studies."

D. The FDA approved the NDA for Victoza with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of Victoza outweigh the risks, including specifically, the potential risk of MTC.

E. As relevant to this Agreement, the REMS required Novo Nordisk to develop and implement a Communication Plan, which included specific steps for communicating information to healthcare providers about the potential risk of MTC. The Victoza REMS Communication Plan required Novo Nordisk to communicate this information in various forms including in a letter to likely prescribers, and in a "Highlighted Information for Prescribers" ("HIP-D") document provided by Novo Nordisk sales representatives who met with healthcare providers for the primary purpose of increasing the number of Victoza prescriptions those healthcare providers issued.

F. In March 2011, as part of its ongoing REMS obligations, Novo Nordisk conducted surveys of endocrinologists and primary care physicians who identified themselves as physicians who prescribe medications for patients with Type 2 diabetes to gauge their awareness and understanding of the potential risks of MTC associated with Victoza. The survey showed that only approximately half of primary care physicians surveyed were aware of the boxed warning on the Victoza labeling that explained the potential risk of MTC associated with Victoza. On May 5, 2011, the FDA informed Novo Nordisk that the FDA considered the "lack of knowledge among primary care physicians of the boxed warning for thyroid C-cell tumors" to be "new safety information" under the REMS. Based on this "new safety information," the FDA

informed Novo Nordisk that a modification to the REMS, to include an additional letter to primary care physicians, was necessary. The letter was intended to increase awareness of the potential risk of MTC associated with Victoza among primary care physicians. Novo Nordisk worked with the FDA to draft the letter to be provided to primary care physicians.

G. The Relators listed herein have filed the following civil actions against Novo Nordisk (collectively the "Civil Actions"):

(1) On October 15, 2010, Elizabeth Kennedy filed an action in the United States District Court for the Southern District of Texas captioned *United States, et al., ex rel. Elizabeth Kennedy, v. Novo A/S, et al.*, Civ. Action No. 10-cv-3856 (S.D. TX) (the " Kennedy Action"). The Kennedy Action was transferred to the United States District Court for the District of Columbia on September 12, 2013, and is captioned *United States, et al., ex rel. Elizabeth Kennedy v. Novo A/S, et al. No. 13-cv-01529.*

(2) On December 28, 2010, Peter Dastous filed an action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Peter Dastous et al. v. Novo Nordisk, Inc., et al.*, Civ. Action No. 10-cv-12247-GAO (D. Mass.) (the "Dastous Action"). The Dastous action was transferred to the United States District Court for the District of Columbia on September 7, 2011, and is captioned *United States, et al. ex rel. Peter Dastous, et al. v. Novo Nordisk,* Civ. Action No. 11-cv-01662 (D.D.C.)

(3) On January 12, 2011, Leslie Ferrara and Shelly Kelling filed an action in the United States District Court for the District of Columbia captioned *United States, et al., ex rel.* Leslie Ferrara and Shelly Kelling *v. Novo Nordisk, Inc., et al.*, Civ. Action No. 1:11-cv-00074 (D.D.C.). (the "Ferrara Kelling Action"). Ferrara and Kelling filed an Amended Complaint on June 21, 2011, a Second Amended Complaint on June 6, 2013, and a Third Amended Complaint on November 19, 2015.

(4) On September 2, 2011, David Myers filed an action in the United States District Court for the District of Columbia captioned *United States, et al., ex rel. David Myers v. Novo Nordisk, Inc.*, Civ. Action No. 11-cv-1596 (D.D.C.). (the "Myers Action"). Myers filed an Amended Complaint on September 24, 2012.

(5) On May 23, 2012, McKenzie Stepe filed an action in the United States District Court for the District of New Jersey captioned *United States, et al., ex rel. McKenzi Stepe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 12-cv-3223 (D. N.J.). (the "McKenzie Stepe Action"). The McKenzi Stepe action was transferred to the United States District Court for the District of Columbia on February 7, 2013, and is captioned *United States, et al., ex rel. Mckenzi Stepe v. Novo Nordisk, Inc.*, Civ. Action No. 13-221 (D.D.C.).

(6) On February 22, 2016, [John Doe and Jane Doe filed a *qui tam* action in the United States District Court for the Northern District of Texas

captioned *United States, et al., ex rel. John Doe and Jane Doe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 3:16-CV-486-L (N.D. Tex.) (the "Doe Action").

H. Novo Nordisk has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement) hereinafter referred to as the "United States."

I. The State contends that Novo Nordisk caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396w-5), including managed care entities as defined by 42 U.S.C. § 1396u-2.

J. The State contends that it has certain civil and administrative causes of action against Novo Nordisk for engaging in the following conduct concerning the marketing, promotion, and sale of Victoza from January 1, 2010, through December 31, 2014:

i. The FDA specifically required the REMS Communication Plan as part of the NDA approval for Victoza. After Victoza was approved, Novo Nordisk provided the sales force with training to appropriately implement the REMS, but also provided them with information that had the overall effect of arming them with messages that could create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant. Following the training, certain Novo Nordisk sales representatives made false or

misleading statements that were designed to avoid and circumvent the requirements of the Victoza REMS Communication Plan. Those statements included:

a. the potential risk of MTC associated with Victoza is only applicable to rats and mice;

b. all diabetes drugs have boxed warnings and Victoza is no different and no less safe than those other drugs;

c. because of differences between rodents and humans it is implausible that humans would contract MTC from the use of Victoza;

d. physicians should not be concerned about MTC because it is easy to treat if a patient does get it;

e. "sandwiching" the MTC risk information between promotional messages; and

f. when delivering to primary care physicians a letter required by the May 5, 2011 modification to the Victoza REMS, certain Novo Nordisk sales representatives, executing instructions from Novo Nordisk's Vice President, Diabetes Marketing, told primary care physicians in June 2011 that there were no new safety concerns with Victoza and that the letter was simply the second part of the REMS requirement, which was a false or misleading message and contradicted the REMS modification that FDA deemed to be "new safety information."

ii. Novo Nordisk knowingly promoted the sale to and use of Victoza by adult patients who did not have Type 2 diabetes, a use for which it was not approved as safe and effective by the FDA, that was not a medically accepted indication as defined by 42 U.S.C. § 1396-8, and not covered by the State's Medicaid Program.

As a result, the State alleges that Novo Nordisk caused false or fraudulent claims for Victoza to be submitted to the State's Medicaid Program. This conduct is referred to as the "Covered Conduct."

K. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Novo Nordisk nor a concession by the State that its claims are not well founded.

L. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Novo Nordisk agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of Forty-Six Million Five Hundred Thousand Dollars ($46.5 million) plus interest at a rate

of 1.625% from December 7, 2016 until the date of payment (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Novo Nordisk shall pay to the United States the sum of $43,179,036.90, plus accrued interest on that amount at the rate of 1.625% per annum commencing on December 7, 2016 until the date of payment ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Novo Nordisk shall pay to the Medicaid Participating States the sum of $3,320,963.13, ("Medicaid State Settlement Amount"), plus accrued interest on that amount at the rate of 1.625% per annum commencing on December 7, 2016 until the date of payment, subject to the non-participating state deduction provision of Sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 45 day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Novo Nordisk.

(c) Novo Nordisk shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Novo Nordisk and the State Team have agreed, or in a form otherwise agreed to by Novo Nordisk and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Novo Nordisk's attorneys within 45 days of receiving this Agreement. If this condition is not satisfied within 45 days, Novo Nordisk's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Novo Nordisk and the State Team to extend the 45 day period.

(d) The total portion of the amount paid by Novo Nordisk in settlement for the Covered Conduct for the State is $301,612.43, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $96,633.61, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 45 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Novo Nordisk absent written agreement between counsel for Novo Nordisk's and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Novo Nordisk in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Action. Contingent upon the receipt of their respective State Amounts, the State, if served with the Civil Action and liable to pay a Relator's share,

agrees to pay the Relator(s) through the State Team an amount to be determined by court hearing or agreement.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Novo Nordisk set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release Novo Nordisk, together with its current and former direct and indirect parent corporations and limited liability companies; its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their respective current and former corporate owners; and the predecessors, successors, transferees, and assigns of any of them (collectively, the "Novo Nordisk Released Entities") from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including the Novo Nordisk Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following

claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(g) any liability for express or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. Novo Nordisk waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, Novo Nordisk waives and discharges the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Novo Nordisk has against the State, its agencies,

employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Novo Nordisk must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and Novo Nordisk agrees not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of or not to appeal or cause the appeal of any such denials of claims.

8. Novo Nordisk shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

9. Novo Nordisk expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

10. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

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

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any liability against any other person or entity, except to the extent provided for in Paragraphs 3, 6, and 8.

13. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

14. In addition to all other payments and responsibilities under this Agreement, Novo Nordisk agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Novo Nordisk will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

15. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

16. The undersigned Novo Nordisk signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

17. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

18. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

19. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF NORTH CAROLINA

By: _____ Dated: 5/23/2017

CHARLES H. HOBGOOD
Director, Medicaid Investigations Division
Office of the Attorney General

By: _____ Dated: 5/15/2017

DAVE RICHARD
Deputy Secretary for Medical Assistance
Division of Medical Assistance

Novo Nordisk

By: _____ Dated: 7/21/2017

[Name] Curtis O'Meara
[Title] CVP & General Counsel

By: _____ Dated: 7/19/17

Counsel to NNI

(May need multiple blocks)