

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; the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”); and the United States Department of Veteran Affairs (collectively, the “United States”); Novo Nordisk Inc. (“Novo Nordisk”); and Relators identified in the cases listed in Recital G of this Agreement (“Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

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 risk 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. Pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), 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. Kennedy v. Novo A/S, et al.*, Civ. Action No. 10-CV-3856. The 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. Kennedy v. Novo A/S, et al.*, Civ. Action No. 13-cv-1529.
- (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. Dastous v. Novo Nordisk, Inc.*, Civ. Action No. 10-CA-12247. The 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. Dastous v. Novo Nordisk, Inc.*, Civ. Action No. 11-01662.
- (3) On January 12, 2011, Lesley 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. Ferrara, et al. v. Novo Nordisk, Inc., et al.*, Civ. Action No. 1:11-cv-00074. 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. Myers v. Novo Nordisk, Inc.*, Civ. Action No. 1:11-cv-01596. 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. Stepe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 12-3223. The 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. Stepe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 1:13-cv-00221.
- (6) On February 22, 2016, Kathy Ann Gratton and Raymond Hippolyte filed a *qui tam* action in the United States District Court for the Northern District of Texas captioned *United States, et al., ex rel. Doe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 3-16-CV-486. The action was transferred to the United States District Court for the District of Columbia on April 28, 2017, and is captioned *United States, et al., ex rel. Doe v. Novo Nordisk, Inc., et al.*, Civ. Action No. 1:17-00791.
- (7) On August 8, 2016, Greg Smith, Clint Houck, and Brent Shirkey filed a *qui tam* action in the United States District Court for the District of Columbia captioned *United States ex rel. Smith, et al. v. Novo Nordisk, Inc.*, Civ. Action No. 16-1605. Smith, Houck, and Shirkey filed an Amended Complaint on October, 12, 2016.

H. Contemporaneous with the execution of this Agreement, Novo Nordisk will enter into a separate agreement with the United States of America to resolve an action brought in the

United States District Court for the District of Columbia under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332, arising from the sale of Victoza (“FDCA Settlement Agreement”).

I. Novo Nordisk has entered or will be entering into separate settlement agreements, described in Paragraph 1(b) below (the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the Covered Conduct, defined below. States with which Novo Nordisk executes a Medicaid State Settlement Agreement in the form to which Novo Nordisk and the National Association of Medicaid Fraud Control Units (“NAMFCU”) have agreed, or in a form otherwise agreed to by Novo Nordisk and an individual State, shall be defined as “Medicaid Participating States.”

J. The United States contends that Novo Nordisk submitted or caused to be submitted claims for payment for Victoza to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914; and caused the purchase of Victoza by the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17 (“VA”) (collectively the “Federal Health Care Programs”).

K. The United States contends that it and the Medicaid Participating States have certain civil claims against Novo Nordisk arising from 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 II 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 Federal Health Care Programs.

As a result of the foregoing conduct, the United States alleges that Novo Nordisk caused false or fraudulent claims for Victoza to be submitted to, or caused purchases by, the Federal Health Care Programs. This conduct is referred to below as the “Covered Conduct.”

L. 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 United States that its claims are not well founded.

M. Certain Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement.

N. Certain Relators claim entitlement to recover from Novo Nordisk reasonable expenses, attorneys’ fees and costs, pursuant to 31 U.S.C. § 3730(d), and, in their separate Civil Actions, certain Relators assert claims against Novo Nordisk for conduct other than the Covered Conduct, claims arising from the Relator’s employment, or claims under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871 *et seq.* and the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92. Contemporaneous with the execution of this Agreement, Novo Nordisk, Relators, and Relators’ counsel will be entering into separate agreements to resolve such claims.

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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Novo Nordisk shall pay to the United States and the Medicaid Participating States, collectively, 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 (“Total Settlement Amount”).

a. Novo Nordisk shall pay to the United States the sum of \$43,179,036.87 plus accrued interest as set forth above (“Federal Settlement Amount”) no later than five days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Department of Justice.

b. Novo Nordisk shall pay to the Medicaid Participating States the sum of \$3,320,963.13 plus accrued interest as set forth above (“Medicaid State Settlement Amount”). The Medicaid State Settlement Amount shall be paid pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Novo Nordisk will enter into with the Medicaid Participating States.

2. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Novo Nordisk’s full payment of the Total Settlement Amount, the United States releases Novo Nordisk, together with its current and former direct and indirect parent corporations and limited liability companies (“Parents”); 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, 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; any statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Pt. 0, Subpart I, § 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Except as otherwise provided in separate agreements between Relators and Novo Nordisk and conditioned upon Novo Nordisk's full payment of the Total Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Novo Nordisk, together with its current and former Parents; 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 corporate predecessors, successors, transferees and assigns of any of them; and its and their past, present and future owners, officers, directors, employees, and attorneys, in their individual and official capacities, 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, and from any and all claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses 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 statute or regulation, or in common law, that Relators, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring arising from or relating to the claims Relators asserted or could have asserted in the Civil Actions against Novo Nordisk or its current and former Parents; 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 corporate predecessors, successors, transferees and assigns of any of them, provided, however, that nothing in this paragraph precludes Relators' attorneys from bringing any claims on behalf of a client other than Relators against Novo Nordisk that are unrelated to the Covered Conduct.

4. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against Novo Nordisk from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).

5. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims 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. Any administrative liability, 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; and

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

6. 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), and that the portions of the Total Settlement Amount allocated to the Covered Conduct set forth in Paragraph K(i) (\$43,970,000) and Paragraph K(ii) (\$2,530,000) are also fair, adequate, and reasonable under all the circumstances. In connection with this Agreement and the Civil Actions, Relators and their heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Actions, nor any dismissal of the Civil Actions, shall waive or otherwise affect the ability of the Parties to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(b)(5), 3730(d)(3) and 3730(e), bar Relators from sharing in the proceeds of this Agreement or recovering attorneys' fees, costs, and expenses pursuant to § 3730(d). Moreover, the Parties and Relators' heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relators should receive of any proceeds of the settlement of their claims, and that no agreements concerning Relator share have been reached to date.

7. Novo Nordisk waives and shall not assert any defenses Novo Nordisk 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. Nothing in this paragraph or any other provision of this Agreement

constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. Novo Nordisk 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 Novo Nordisk 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.

9. Conditioned upon Relators' execution of this Agreement and dismissal with prejudice as to Relators of the Civil Actions as set forth more fully in Paragraph 14, Novo Nordisk, together with its current and former Parents; 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 corporate predecessors, successors, transferees and assigns of any of them; release Relators, their heirs, successors, attorneys, agents, and assigns, from any and all claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages, punitive damages, costs and expenses 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 statute or regulation, or in common law, that Novo Nordisk has against Relators, their heirs, successors, attorneys, agents and assigns arising from or relating to the claims Relators asserted or could have asserted in the Civil Actions.

10. The Total 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, FEHPB, the VA, or any state payor, related to the Covered Conduct; and Novo Nordisk agrees not to resubmit to any Medicare contractor, TRICARE, FEHPB, the VA, or any state payor 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.

11. Novo Nordisk 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Novo Nordisk, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and the FDCA Settlement Agreement;
- (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (3) Novo Nordisk's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement and the FDCA Settlement Agreement; and
- (5) the payment Novo Nordisk makes to the United States pursuant to this Agreement and any payments that Novo Nordisk 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, VA and the FEHBP (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Novo Nordisk, and Novo Nordisk 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 Novo Nordisk or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Novo Nordisk 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, VA 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 Novo Nordisk 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. Novo Nordisk agrees that the United States, at a minimum, shall be entitled to recoup from Novo Nordisk 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 Novo Nordisk or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in

this Paragraph) on Novo Nordisk 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 Novo Nordisk's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

12. 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 Paragraphs 2, 3, 8, 9, and 13 (waiver for beneficiaries paragraph).

13. Novo Nordisk 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.

14. After Novo Nordisk pays the Federal Settlement Amount described in Paragraph 1, above, the United States and Relators shall promptly file a stipulation of dismissal in each Civil Action. Each stipulation of dismissal shall be with prejudice to Relators as to all claims against Novo Nordisk in the Civil Action, with prejudice to the United States as to the Covered Conduct pursuant to and consistent with the terms and conditions of this Agreement, and without prejudice to the United States as to any other claims in the Civil Action against Novo Nordisk. The stipulation shall provide that Relators' claims for a share of the proceeds of the Federal Settlement Amount pursuant to 31 U.S.C. § 3730(d) or the Medicaid State Settlement Amount pursuant to any similar state statute shall not be dismissed until they are settled, adjudicated or otherwise resolved, and shall further provide that the Court shall retain jurisdiction to adjudicate,

if necessary, any Relator's claim for a share of the proceeds of the Civil Action pursuant to 31 U.S.C. § 3730(d) and pursuant to any similar state statute.

15. Except as otherwise provided in separate agreements between Relators and Novo Nordisk referenced in Paragraph N, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

17. 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 Columbia. 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.

18. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

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

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

21. This Agreement is binding on Novo Nordisk's successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

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

24. 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: 7/26/17

BY: William E Olson
WILLIAM E. OLSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DARRELL C. VALDEZ
Assistant United States Attorney
United States Attorney's Office for the District of
Columbia

DATED: _____

BY: _____
LISA M. RE
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: _____
BRYAN T. WHEELER
Deputy General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

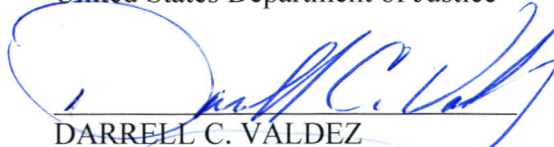
BY: _____
SYLVIA V. PULLEY
Acting Assistant Director of Federal
Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

WILLIAM E. OLSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice



DARRELL C. VALDEZ
Assistant United States Attorney
United States Attorney's Office for the District of
Columbia

DATED: _____

BY: _____

LISA M. RE
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: _____

BRYAN T. WHEELER
Deputy General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____

SYLVIA V. PULLEY
Acting Assistant Director of Federal
Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

WILLIAM E. OLSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DARRELL C. VALDEZ
Assistant United States Attorney
United States Attorney's Office for the District of
Columbia

DATED: 07/25/12

BY: Lisa M Re

LISA M. RE
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: _____

BRYAN T. WHEELER
Deputy General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____

SYLVIA V. PULLEY
Acting Assistant Director of Federal
Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

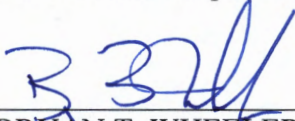
BY: _____
WILLIAM E. OLSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DARRELL C. VALDEZ
Assistant United States Attorney
United States Attorney's Office for the District of
Columbia

DATED: _____

BY: _____
LISA M. RE
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: 7/24/17

BY: 

BRYAN T. WHEELER
Deputy General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
SYLVIA V. PULLEY
Acting Assistant Director of Federal
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United States Office of Personnel Management

THE UNITED STATES OF AMERICA

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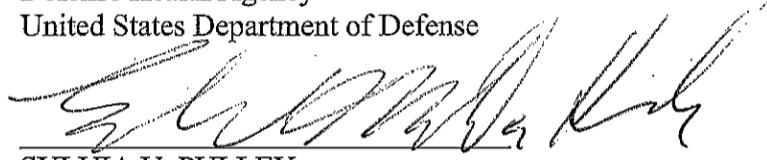
DATED: _____

BY: _____
LISA M. RE
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: _____
BRYAN T. WHEELER
Deputy General Counsel
Defense Health Agency
United States Department of Defense

DATED: 7/25/17


BY: 
for SYLVIA V. PULLEY
Acting Assistant Director of Federal
Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

NOVO NORDISK INC.

DATED: 7/20/17

BY: 
CURT OLTMANS
General Counsel, Novo Nordisk Inc.

DATED: 7/20/17

BY: 
PAUL E. KALB
JAIME L.M. JONES
Sidley Austin LLP
Counsel for Novo Nordisk Inc.

ELIZABETH KENNEDY - RELATOR

DATED: _____

BY: _____
ELIZABETH KENNEDY

DATED: _____

BY: _____
SARAH M. FRAZIER
Berg & Androphy
Counsel for Elizabeth Kennedy

PETER DASTOUS - RELATOR

DATED: _____

BY: _____
PETER DASTOUS

DATED: _____

BY: _____
ERIKA A. KELTON
LARRY P. ZOGLIN
Phillips & Cohen LLP
Counsel for Peter Dastous

Employee Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

NOVO NORDISK INC.

DATED: _____

BY: _____

CURT OLTMANS

General Counsel, Novo Nordisk Inc.

DATED: _____

BY: _____

PAUL E. KALB

JAIME L.M. JONES

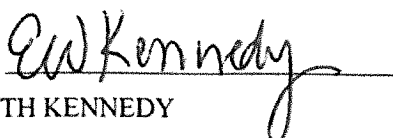
Sidley Austin LLP

Counsel for Novo Nordisk Inc.

ELIZABETH KENNEDY - RELATOR

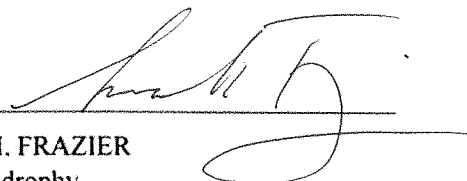
DATED: 7/24/17

BY: _____


ELIZABETH KENNEDY

DATED: 7/24/17

BY: _____


SARAH M. FRAZIER

Berg & Androphy

Counsel for Elizabeth Kennedy

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DATED: _____

BY: _____
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Berg & Androphy
Counsel for Elizabeth Kennedy

PETER DASTOUS - RELATOR

DATED: 7/21/17

BY: Peter Dastous
PETER DASTOUS

DATED: 7/21/17

BY: Erika A. Kelton
ERIKA A. KELTON
LARRY P. ZOGLIN
Phillips & Cohen LLP
Counsel for Peter Dastous

LESLEY FERRARA AND SHELLY KELLING - RELATORS

DATED: 7-22-17 BY: Lesley Ferrara
LESLEY FERRARA

DATED: _____ BY: _____
SHELLY KELLING

DATED: _____ BY: _____
ANN LUGBILL
MARK HANNA
MurphyAnderson PLLC
Counsel for Lesley Ferrara and Shelly Kelling

DAVID MYERS - RELATOR

DATED: _____ BY: _____
DAVID MYERS

DATED: _____ BY: _____
GREGORY Y. PORTER
Bailey & Glasser LLP
Counsel for David Myers

DATED: _____ BY: _____
TODD BAILESS
Bailess Smith PLLC
Counsel for David Myers

McKENZIE STEPE - RELATOR

DATED: _____ BY: _____
McKENZIE STEPE

DATED: _____ BY: _____
DAVID STONE
ROBERT MAGNANINI
Stone & Magnanini LLP
Counsel for McKenzie Stepe

LESLEY FERRARA AND SHELLY KELLING - RELATORS

DATED: _____ BY: _____
LESLEY FERRARA

DATED: July 21, 2017 BY: Shelly Kelling by
SHELLY KELLING Ann Luginil,
Power of Attorney

DATED: _____ BY: _____
ANN LUGBILL
MARK HANNA
MurphyAnderson PLLC
Counsel for Lesley Ferrara and Shelly Kelling

DAVID MYERS - RELATOR

DATED: _____ BY: _____
DAVID MYERS

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McKENZIE STEPE - RELATOR

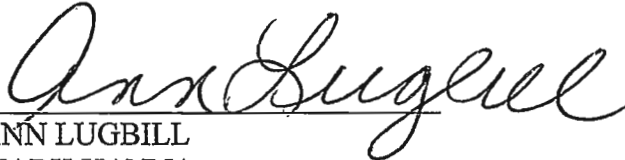
DATED: _____ BY: _____
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DAVID MYERS - RELATOR

DATED: 7/24/17 BY: *David Myers*
DAVID MYERS

DATED: _____ BY: *Gregory Y. Porter*
GREGORY Y. PORTER
Bailey & Glasser LLP
Counsel for David Myers

DATED: 7/24/17 BY: *Todd Bailess*
TODD BAILESS
Bailess Smith PLLC
Counsel for David Myers

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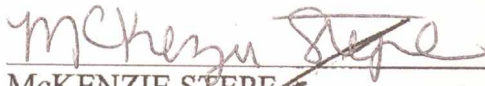
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McKENZIE STEPE

DATED: 7/21/17 BY: 
DAVID STONE
ROBERT MAGNANINI
Stone & Magnanini LLP
Counsel for McKenzie Stepe

KATHY ANN GRATTON and RAYMOND HIPPOLYTE- RELATOR

DATED: 7/21/17

BY: *Kathy Ann Gratton*
KATHY ANN GRATTON

DATED: _____

BY: _____
RAYMOND HIPPOLYTE

DATED: _____

BY: _____
CHRISTOPHER L. NELSON
ROSS M. WOLFE
The Weiser Law Firm, P. C.
Counsel for Kathy Ann Gratton and Raymond Hi

GREG SMITH, CLINT HOUCK, AND BRENT SHIRKEY - RELATOR

DATED: _____

BY: _____
GREG SMITH

DATED: _____

BY: _____
CLINT HOUCK

DATED: _____

BY: _____
BRENT SHIRKEY

KATHY ANN GRATTON and RAYMOND HIPPOLYTE- RELATORS

DATED: _____

BY: _____
KATHY ANN GRATTON

*by CLW
w/ express authorization*

DATED: 7/25/17

BY: Raymond Hippolyte
RAYMOND HIPPOLYTE

DATED: 7/25/17

BY: [Signature]
CHRISTOPHER L. NELSON
ROSS M. WOLFE
The Weiser Law Firm, P. C.
Counsel for Kathy Ann Gratton and Raymond Hippolyte

GREG SMITH, CLINT HOUCK, AND BRENT SHIRKEY - RELATORS

DATED: _____

BY: _____
GREG SMITH

DATED: _____

BY: _____
CLINT HOUCK

DATED: _____

BY: _____
BRENT SHIRKEY

DATED: _____

BY: _____
SUZANNE E. DURRELL
Durrell Law Office
LEE GLASS
NEIL A. ROBERTS
Protectus Law
Counsel for Greg Smith, Clint Houck, and Brent Shirkey

ROBERT MAGNANINI
Stone & Magnanini LLP
Counsel for McKenzie Stepe

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KATHY ANN GRATTON

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RAYMOND HIPPOLYTE

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ROSS M. WOLFE
The Weiser Law Firm, P. C.
Counsel for Kathy Ann Gratton and Raymond Hippolyte

GREG SMITH, CLINT HOUCK, AND BRENT SHIRKEY - RELATORS

DATED: 7/21/2017 BY: 
GREG SMITH

DATED: _____ BY: _____
CLINT HOUCK

DATED: _____ BY: _____
BRENT SHIRKEY

DATED: _____ BY: _____
SUZANNE E. DURRELL
Durrell Law Office

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KATHY ANN GRATTON

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RAYMOND HIPPOLYTE

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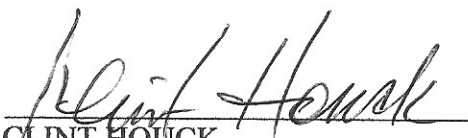
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GREG SMITH, CLINT HOUCK, AND BRENT SHIRKEY - RELATORS

DATED: _____

BY: _____
GREG SMITH

DATED: 7/22/2017

BY: 
CLINT HOUCK

DATED: _____

BY: _____
BRENT SHIRKEY

DATED: _____

BY: _____
SUZANNE E. DURRELL
Durrell Law Office
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RAYMOND HIPPOLYTE

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Counsel for Kathy Ann Gratton and Raymond Hippolyte

GREG SMITH, CLINT HOUCK, AND BRENT SHIRKEY - RELATORS

DATED: _____ BY: _____
GREG SMITH

DATED: _____ BY: _____
CLINT HOUCK

DATED: 7/23 BY: 
BRENT SHIRKEY

DATED: _____ BY: _____
SUZANNE E. DURRELL
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LEE GLASS
NEIL A. ROBERTS
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Counsel for Greg Smith, Clint Houck, and Brent Shirkey

KATHY ANN GRATTON and RAYMOND HIPPOLYTE- RELATORS

DATED: _____

BY: _____
KATHY ANN GRATTON

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RAYMOND HIPPOLYTE

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DATED: _____

BY: _____
GREG SMITH

DATED: _____

BY: _____
CLINT HOUCK

DATED: _____

BY: _____
BRENT SHIRKEY

DATED: 7/22/17

BY: *Suzanne E. Durrell*

SUZANNE E. DURRELL
Durrell Law Office
LEE GLASS
NEIL A. ROBERTS
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Counsel for Greg Smith, Clint Houck, and Brent Shirkey