

**ATTORNEY GENERAL OF THE STATE OF NEW YORK
BUREAU OF CONSUMER FRAUDS AND PROTECTION**

In the Matter of

**Investigation by LETITIA JAMES,
Attorney General of the State of New York, of**

Novo Nordisk Inc.,

Respondent.

SETTLEMENT AGREEMENT

The Office of the Attorney General of the State of New York (“OAG”) commenced an investigation pursuant to Executive Law § 63(12) and General Business Law §§ 349 and 350 into Novo Nordisk Inc. (“NNI”)’s practices related to marketing and pricing for insulin products. This Settlement Agreement (“Agreement”) contains the OAG’s findings from its investigation, and the relief agreed to by the OAG and NNI, whether acting through its respective directors, officers, employees, representatives, agents, and/or subsidiaries (collectively, the “Parties”).

Definitions

1. For the purpose of this Agreement, the definitions in paragraphs 2 through 10 apply.
2. “Affordability Programs” means the following initiatives undertaken by NNI to reduce the out-of-pocket cost of its Insulin Products for eligible consumers based on certain criteria or program requirements: NNI’s Patient Assistance Program, My\$99Insulin, Immediate

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Supply, and an offering that NNI will launch on or before September 27, 2023 through which NNI will offer New York residents without Health Coverage (as defined herein) the option to pay no more than \$35 per month (up to three vials or two packs of pens) for NNI Insulin Products (as defined herein) (the “\$35 Insulin Offering”).

3. “Affordability Programs Website” means the web page or set of web pages specifically maintained by NNI to disseminate information about its Affordability Programs, such as www.novocare.com.

4. “BIN” refers to the Bank Identification Number typically associated with a health insurance provider and that is used in routing and processing pharmacy claims, including but not limited to any regular “cash” BIN a pharmacy may utilize for uninsured customers.

5. “Cash Customer” refers to New York residents filling a prescription for a NNI Insulin Product in a pharmacy located in New York where the patient does not present proof of any form of Health Coverage (as defined herein).

6. “Clear and Conspicuous” (including “Clearly and Conspicuously”) means that the statement, representation, or term being disclosed is of such size, color, contrast, and/or audibility and is so presented as to be readily noticed and understood by the person to whom it is being disclosed. If such statement is necessary as a modification, explanation or clarification to other information with which it is presented, it must be presented in close proximity to the information it modifies, in a manner so as to be readily noticed and understood.

7. “Effective Date” means the date upon which this Agreement has been fully executed by all of the signatories below.

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8. “Health Coverage” means any form of insurance provided by a commercial health care insurer, health maintenance organization, employer-sponsored health plan, government program (such as Medicare or Medicaid), or other source.

9. “Insulin Product” means the following products and any unbranded biologic versions of the branded products, in all cases for as long as NNI markets those products for sale in the United States:

- NovoLog® (insulin aspart) injection 100 U/ml;
- NovoLog® Mix 70/30) (insulin aspart protamine and insulin aspart) injectable suspension 100 U/ml;
- Levemir® (insulin detemir) injection 100 U/ml;
- Tresiba® (insulin degludec) injection 100 U/ml, 200 U/ml;
- Fiasp® (insulin aspart injection) 100 U/ml;
- Novolin® N vial (isophane insulin human suspension) 100 U/ml;
- Novolin® R vial (insulin human injection) 100 U/ml;
- Novolin® 70/30 vial (70% human insulin isophane suspension and 30% human insulin injection) 100 U/ml;
- Novolin® 70/30 FlexPen® (human insulin isophane suspension and human insulin injection) 100 U/ml;
- Insulin Aspart Injection 100 U/ml;
- Insulin Aspart Protamine and Insulin Aspart Injectable Suspension Mix 70/30 100 U/ml;
and
- Insulin Degludec Injection 100 U/ml, 200 U/ml.

10. “Third-Party Messaging Company” means a company that provides messaging services to New York pharmacies in its network, such as Change Healthcare’s eRx or RelayHealth.

OAG Findings

11. According to a 2018 study, approximately 7.4 million Americans with diabetes rely on injected insulin.¹ In New York, as of 2019, an estimated 1.6 million, or 10.5 percent, of adult New York residents have diabetes.² Of those, it is estimated that 464,000 are insulin-dependent.³ The national population diagnosed with diabetes grew by approximately 640,000 people annually between 2012 and 2018.⁴ The prevalence of diabetes is expected to continue to rise over time as the population grows and ages,⁵ with an estimated 1.4 million new diagnoses in 2019.⁶ ⁷ The COVID-19 pandemic has exacerbated diabetes-related problems. Studies have linked COVID-19 to a rise in new diabetes diagnoses and increased complications.⁸

¹ Cefalu, W. T. *Insulin Access and Affordability Working Group: Conclusions and Recommendations*. *Diabetes Care* (June 2018), 41(6): 1299-1311, available at <https://doi.org/10.2337/dci18-0019>.

² CDC, *The Diabetes Atlas*, available at <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html>. See also CDC, BRFSS Brief, 2019, available at https://www.health.ny.gov/statistics/brfss/reports/docs/2021-21_brfss_diabetes.pdf.

³ NYC Health, *Community Health Survey*, available at <https://a816-health.nyc.gov/hdi/epiquery/visualizations?PageType=ts&PopulationSource=CHS&Topic=1&Subtopic=24> (calculated figure is an estimate based on New York City data).

⁴ CDC, *The Diabetes Atlas*, available at <https://gis.cdc.gov/grasp/diabetes/diabetesatlas-surveillance.html>.

⁵ Lin, J., Thompson, T.J., Cheng, Y.J. *et al.* Projection of the future diabetes burden in the United States through 2060. *Popul Health Metrics* 16, 9 (2018), available at <https://doi.org/10.1186/s12963-018-0166-4>.

⁶ American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, *Diabetes Care* 2018; 41:917–928, 918 (May 2018), available at <https://doi.org/10.2337/dci18-0007>.

⁷ CDC, *National Diabetes Statistics Report, 2020*, available at <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>.

⁸ Sathish T, Kapoor N, Cao Y, Tapp R, Zimmet P. *Proportion of newly diagnosed diabetes in COVID-19 patients: A systematic review and meta-analysis*, *Wiley* (2020), 23(3): 870-874. <https://doi.org/10.1111/dom.14269>. See also Shrestha D.B. *et al.* *New-onset diabetes in COVID-19 and clinical outcomes: A systematic review and meta-analysis*. *World J Virol* (2021), 10(5): 275-287. DOI: 10.5501/wjv.v10.i5.275.

12. Diabetes has disproportionately affected poor New Yorkers. A 2013 publication from the New York Department of Health and Mental Hygiene found that in New York City, those who live in the poorest neighborhoods are 70% more likely to have diabetes (12.7% vs. 7.5%), than those in the wealthiest neighborhoods.⁹ ¹⁰ In 2019, 16.1% of New York adults with diabetes had an annual household income of less than \$25,000, while only 6.3% had an annual household income of over \$50,000.¹¹

13. Over the past 20 years, as the numbers of people diagnosed with diabetes has increased, the list price, or Wholesale Acquisition Cost, of analog insulin has increased significantly. From 2002 to 2013, average list prices for analog insulin products nearly tripled from \$4.34/ml to \$12.92/ml.¹² Other estimates suggest that, between 2014 and 2018, the mean list price for 32 analog insulin products grew by 40.1%, from \$19.60 to \$27.45 per 100 units.¹³ One study conducted of the United States found that 25% of diabetic individuals ration insulin due to the high cost.¹⁴

⁹ See <https://www1.nyc.gov/assets/doh/downloads/pdf/survey/survey-2009diabetes.pdf>.

¹⁰ New York City Department of Health and Mental Hygiene. *Epi Data Brief, 2013*, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/epi/databrief26.pdf>.

¹¹ CDC, *BRFSS Brief, 2019*, available at https://www.health.ny.gov/statistics/brfss/reports/docs/2021-21_brfss_diabetes.pdf.

¹² Hua X, Carvalho N, Tew M, Huang ES, Herman WH, Clarke P. *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*. *JAMA*. (2016);315(13):1400–1402, available at doi:10.1001/jama.2016.0126.

¹³ Van Nuys K, Ribero R, Ryan M, Sood N. *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*. *JAMA Health Forum* (2021), 2(11):e213409, available at doi:10.1001/jamahealthforum.2021.3409.

¹⁴ Rajkumar V, *The High Cost of Insulin in the United States: An Urgent Call to Action*. *Mayo Clinic Proceedings* (2020); 95(1): 22-28, available at <https://doi.org/10.1016/j.mayocp.2019.11.013>.

14. A 2018 study found that, in terms of manufacturing costs of insulin per person per year, regular human insulin (RHI) costs \$48-71 to produce, and analogs cost \$78-133 to produce.¹⁵ A pricing analysis of insulins found that, in 2012, annual spending per person on insulin was \$2,864, which increased to \$5,705 in 2016.¹⁶ During this time period, average insulin point-of-sale prices nearly doubled, with RHI increasing between 93-134%, and insulin analogs increasing by 69-138%.¹⁷ The prices charged for insulin products have increased such that certain categories of consumers, including those who are uninsured, are sometimes unable to afford their prescribed supply without the assistance of an affordability program.

15. Insulin manufacturers set list or Wholesale Acquisition Cost prices for insulin. These list prices are used as an input to determine the prices at which health plans reimburse pharmacies for prescriptions. Pharmacy benefit managers (“PBMs”), which represent health insurance plans, negotiate with manufacturers and pharmacies on behalf of the health insurance plans they represent. In order to obtain favorable placement on a health plan’s formulary, which makes such products widely available through co-pays, insulin manufacturers often offer to rebate a portion of insulin’s list price to PBMs. These rebates often take the form of percentage discounts off the list prices. Higher list prices may result in larger rebates to the PBMs. The enhanced value of these rebates redounds to the benefit of the PBMs (or, in some cases, the

¹⁵ Gotham D., Barber M.J., Hill A., *Production costs and potential prices for biosimilars of human insulin and insulin analogues*, *BMJ Global Health* (2018);3:e000850 available at <https://gh.bmj.com/content/3/5/e000850>. The authors assume a dosage of 40 units/day, which is the World Health Organization defined daily dose for insulin.

¹⁶ Biniek, J. F., Johnson, W. *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*. *Health Care Cost Institute* (Jan 2019). Brief available at <https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>.

¹⁷ *See id.*

health plans that the PBMs represent); in addition, PBMs frequently capture administrative fees from pharmaceutical manufacturers that are related to the list prices of drugs.

16. Because insulin list prices are not paid by the vast majority of patients, but can be a factor in determining the prices charged at the point of sale, certain categories of consumers are presented with pharmacy retail prices that are much higher than the discounted prices negotiated by certain PBMs and/or large health insurance plans. For example, analog insulin users with certain high deductible health plans, which require them to pay a percentage of the cost of the product until they reach a certain monetary amount, may pay prices tied to the list price or Wholesale Acquisition Cost of insulin for a certain portion of the year. Uninsured purchasers of analog insulin who have not enrolled in an available affordability program and who do not receive insulin from a clinic or other source will frequently be faced with an insulin price tied to the list price.

17. NNI has developed a number of affordability programs in order to help patients who use NNI Insulin Products receive free insulin or to reduce their out-of-pocket costs for these products.

18. Some consumers eligible for NNI's Affordability Programs are not enrolled in them, and thus do not benefit from the significant cost savings available through these programs. This may be due, in part, to a lack of awareness of their eligibility for these programs.

19. NNI neither admits nor denies the OAG Findings set forth in paragraphs 11-18 of this Agreement.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the Parties:

Prospective Relief

Continuing Affordability Programs

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20. NNI shall continue to make Affordability Program offerings for Insulin Products to New York residents who have a valid prescription for an NNI Insulin Product, substantially as described herein, on terms and conditions at least as favorable to Cash Customers as the terms and conditions that apply to those programs as of the Effective Date of this Agreement, including but not limited to:

- a. The My\$99Insulin program, which offers the option to pay no more than \$99, or no more than the lowest applicable statutory cap (under federal or New York law) for the commercially insured, whichever is lower, for a monthly supply of NNI Insulin Products (up to three vials or two packs of pens);
- b. For New York residents with a total household income at or below 400% of the federal poverty level who are not commercially insured and who do not participate in or seek reimbursement from any federal or state health care program with prescription drug coverage, NNI shall offer insulin at no cost in accordance with the terms of its Patient Assistance Program;
- c. For New York residents who attest to being at risk of rationing insulin due to financial hardship, who do not participate in or seek reimbursement from any federal or state health care program with prescription drug coverage, NNI shall continue to offer an Immediate Supply of up to 35 mL of any combination of NNI insulins for free once per calendar year in accordance with the terms of its Immediate Supply program.
- d. The \$35 Insulin Offering described above that NNI will launch on or before September 27, 2023.

Pharmacy-Assisted Rapid Affordability Determinations

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21. NNI shall implement the following program, designed to assist Cash Customers to quickly obtain Insulin Products at affordable prices at the point of sale in accordance with the terms of its Affordability Programs by September 27, 2023:

- a. NNI shall contract with Third Party Messaging Companies to provide that, if a pharmacist, at a pharmacy that allows the messaging described herein, processes a Cash Customer's prescription for a NNI Insulin Product to its regular cash BIN, the Third-Party Messaging Companies with which NNI has contracted will provide the pharmacy with a message (the precise language of which NNI will approve) advising the pharmacy that it can facilitate the Cash Customer's ability to access NNI's Affordability Programs for Insulin Products by utilizing (or directing the Cash Customer to utilize) a specified link to the Affordability Programs Website or a specified toll free number. Such messaging shall indicate that the consumer may be eligible for free or substantially discounted insulin.
- b. If a pharmacist at a pharmacy that allows the messaging described herein processes a Cash Customer's prescription for an NNI Insulin Product to a BIN associated with an NNI Affordability Program but the request is rejected because the Cash Customer has not established eligibility for the Affordability Program, the Third Party Messaging Companies with which NNI has contracted will provide the pharmacy with the messaging specified in paragraph 21(a).
- c. Upon receiving a Cash Customer's request to utilize one of its Affordability Programs for Insulin Products, NNI shall determine the Cash Customer's eligibility according to the terms set forth on the then-operative version of the Affordability Programs Website. NNI shall make eligibility determinations as promptly as possible, so as to enable the Cash

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Customer's access to free or discounted Insulin Products in accordance with the terms of the relevant Affordability Program. Upon a determination of eligibility, NNI shall immediately take steps to supply the pharmacist or eligible Cash Customer with an appropriate coupon, voucher, or other notification of program enrollment that includes a BIN that the pharmacy will submit for adjudication of the prescription.

- d. To the extent necessary to enable pharmacists to assist in the enrollment of Cash Customers in connection with the messaging described herein, NNI shall make reasonable modifications to its existing eligibility verification processes by making available a toll-free number for pharmacist calls that will be included in the messaging contemplated by this paragraph, and by training call center employees who receive such calls.
- e. If necessary to execute this program, NNI shall make reasonable modifications to its Affordability Programs Website and educate its call center employees to enable prompt pharmacist-assisted eligibility determinations for its Affordability Programs, and to comply with the foregoing provisions.

Outreach

22. When communicating in New York with patients, pharmacies, and healthcare providers regarding sales, pricing, or other commercial matters relating to NNI Insulin Products, NNI shall disclose its Affordability Programs, and provide information regarding how to access those offerings, as set forth herein:

- a. Clearly and Conspicuously on the Insulin Product pages of NNI's website;
- b. In detailing visits with healthcare providers regarding NNI Insulin Products;

- c. In NNI's written informational materials provided to pharmacies and healthcare providers regarding NNI's Insulin Products; and
- d. In NNI's written sales communications with pharmacies and healthcare providers regarding NNI's Insulin Products.

23. To the extent that NNI receives outreach from the Pharmacists Society of the State of New York, the New York Board of Pharmacy, or from New York pharmacists seeking information about NNI Affordability Programs, NNI shall reasonably respond to such requests, including providing timely information about its NNI Affordability Programs for Insulin Products with the goal of promoting pharmacist knowledge of, and patient utilization of, NNI Affordability Programs for Insulin Products.

Affordability Program Website Accessibility

24. NNI's Affordability Programs Website shall continue to have interactive eligibility screening functionality. This shall allow Insulin Products consumers to review basic eligibility criteria (e.g., insurance status, estimated household income) using checkboxes, drop-down menus, or a similar interface, and be presented with the NNI Affordability Programs for which they may be eligible. This system shall be displayed on either the home page of the Affordability Programs Website or on a page Clearly and Conspicuously indicated on the home page of the Affordability Programs Website. The conclusion of this screening tool shall explain the results in clear language, and shall direct consumers to any steps needed to use the program(s) for which they are eligible.

25. Where a given Affordability Program does not require involvement of a consumer's physician, the Affordability Programs Website shall allow Insulin Products

consumers to input and submit relevant information without leaving the Affordability Programs Website.

26. NNI's Affordability Programs Website shall have a feature that allows consumers to receive electronically for the My\$99Insulin, Immediate Supply, and \$35 Insulin Offering programs any coupon, co-payment card, or other documentation that they must present to a pharmacy for purposes of utilizing those programs.

27. NNI shall offer live support, either via telephone or a live chat feature on its Affordability Programs Website (or both), during regular business hours, for consumers who are using, or are seeking to use, NNI's Affordability Programs for Insulin Products. The telephone number and/or live chat link shall be Clearly and Conspicuously displayed on all pages of the Affordability Programs Website.

28. By September 27, 2023, NNI shall have representatives available either via telephone or live chat feature on its Affordability Programs Website (or both), during regular business hours, who can communicate in Spanish.

Reporting and Recordkeeping

29. Beginning four months after implementation of the messaging program and continuing for a period of three years thereafter, NNI shall submit to the OAG, no later than 45 days after the conclusion of each three-month period, a quarterly report describing with specificity its compliance with the provisions of this Agreement during the prior quarter. Each report shall include, where data regarding the state residency of applicants is available, the following information only with respect to New York pharmacies and residents:

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- a. Information from Third-Party Messaging Companies regarding the number of pharmacies that are participating in the messaging program described above in the section titled “Pharmacy-Assisted Rapid Affordability Determinations” (the “Messaging Program”);
- b. Information from Third-Party Messaging Companies regarding the number of times a message was sent via a Third-Party Messaging Company as a result of the Messaging Program in response to a pharmacist entering a cash BIN;
- c. Number of customers who enrolled in an NNI Affordability Program for Insulin Products and self-identify to NNI as not having Health Coverage;
- d. Representative samples of the informational materials regarding Affordability Programs provided to providers, pharmacies, and patients pursuant to paragraph 22; and
- e. The publicly reported list price or Wholesale Acquisition Cost for NNI’s Insulin Products as of the beginning of the reporting period.

30. NNI shall maintain for at least three years all underlying documentation and data supporting the reports described in Paragraph 29, and shall furnish this documentation and data to the OAG upon request, within 15 business days of such request.

31. NNI shall also be obligated to report any material changes to the terms and conditions of its Affordability Programs that are applicable to Cash Customers within 30 days of the implementation of those changes.

32. In any case where the circumstances warrant, the OAG may require NNI to submit an interim report of compliance upon 30 days’ notice. Any such report shall include, at a minimum, all items specified in Paragraph 29.

Miscellaneous

Subsequent Proceedings.

33. The OAG accepts this Agreement in lieu of commencing a proceeding and agrees not to file, commence, or pursue a statutory proceeding against NNI for violations of Executive Law § 63(12) or GBL Article 22-A, §§ 349 and 350 based on any allegations related to NNI's insulin pricing practices or on conduct described in the OAG's findings in paragraphs 11 through 18 above that occurred prior to the Effective Date.

34. NNI expressly agrees and acknowledges that the OAG may initiate a subsequent investigation, civil action, or proceeding to enforce this Agreement, for violations of the Agreement, or if the Agreement is voided pursuant to paragraph 41, and agrees and acknowledges that in such event:

- a. any statute of limitations or other time-related defenses related to the subject of this Agreement are tolled from and after the Effective Date;
- b. the OAG may use statements, documents or other materials produced or provided by NNI prior to or after the Effective Date in connection with that investigation, civil action, or proceeding; and
- c. any civil action or proceeding must be adjudicated by the courts of the State of New York, and that NNI irrevocably and unconditionally waives, for purposes of matters relating to compliance with or enforceability of this Agreement, any objection based upon personal jurisdiction, inconvenient forum, or venue.

35. If a court of competent jurisdiction determines that NNI has violated the Agreement, and such a determination becomes final and not subject to further appeal, NNI shall

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pay to the OAG the reasonable cost, if any, of obtaining such determination and of enforcing this Agreement, including without limitation legal fees, expenses, and court costs.

Effects of Agreement:

36. This Agreement is not intended for use by any third party in any other proceeding.

37. All terms and conditions of this Agreement shall continue in full force and effect on any successor, assignee, or transferee of NNI. NNI shall include in any such successor, assignment or transfer agreement a provision that binds the successor, assignee or transferee to the terms of the Agreement. No party may assign, delegate, or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the OAG.

38. Nothing contained herein shall be construed as to deprive any person of any private right under the law.

39. Any failure by the OAG to insist upon the strict performance by NNI of any of the provisions of this Agreement shall not be deemed a waiver of any of the provisions hereof, and the OAG, notwithstanding any such failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Agreement to be performed by NNI.

Communications:

40. All notices, reports, requests, and other communications pursuant to this Agreement shall be in writing and shall, unless expressly provided otherwise herein, be given by hand delivery; express courier; or electronic mail at an address designated in writing by the recipient, and shall be addressed as follows:

If to NNI, to:

Steve Benz
Corporate Vice President and General Counsel

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Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
(609) 786-5247
svbz@novonordisk.com

or in his absence, to the person holding the title of Chief Litigation and Employment Counsel.

If to the OAG, to:

Kate Matuschak
Assistant Attorney General
Consumer Frauds and Protection Bureau
New York State Office of the Attorney General
28 Liberty Street
New York, NY 10005
(212) 416-6189
kate.matuschak@ag.ny.gov,

or in her absence, to the person holding the title of Bureau Chief, Consumer Frauds and Protection Bureau.

Representations and Warranties:

41. The OAG has agreed to the terms of this Agreement based on, among other things, the representations made to the OAG by NNI and its counsel and the OAG's own factual investigation as set forth in Findings, paragraphs 11-18 above. NNI represents and warrants that neither it nor its counsel has made any material representations to the OAG that are inaccurate or misleading. If any material representations by NNI or its counsel are later found to be inaccurate or misleading, this Agreement is voidable by the OAG in its sole discretion.

42. Other than the terms set forth herein, no representation, inducement, promise, understanding, condition, or warranty not set forth in this Agreement has been made to or relied upon by NNI or OAG in entering this Agreement.

43. NNI represents and warrants, through the signatures below, that the terms and conditions of this Agreement are duly approved. NNI further represents and warrants that NNI,

by Marc Fishman, as the signatory to this Agreement, is duly authorized to sign this Agreement on behalf of NNI.

General Principles:

44. Unless a term limit for compliance is otherwise specified within this Agreement, NNI's obligations under this Agreement shall terminate after five years. Nothing in this Agreement shall relieve NNI of other obligations imposed by any applicable state or federal law or regulation or other applicable law.

45. NNI agrees not to make or permit to be made any public statement denying any of the OAG Findings in paragraphs 11-18 in the Agreement or creating the impression that the Agreement is without legal basis, except the foregoing limitation shall not apply to or in connection with any court, legal or administrative proceedings or in connection with investigations or enforcement actions by any governmental body, whether at the local, state, or federal level. Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement shall prevent NNI from making any public statement or taking any action consistent with paragraph 19 of this Agreement.

46. Nothing contained herein shall be construed to limit the remedies available to the OAG in the event that the NNI violates the Agreement after its Effective Date.

47. The parties acknowledge that certain of the undertakings set forth herein involve third parties that may be outside of the parties' control, including but not limited to Third-Party Messaging Companies, pharmacies, and individual pharmacists. In the event that NNI believes that any third party is interfering with the purpose of the agreement, the parties agree to confer in good faith about steps that either or both may be able to take to encourage cooperation by third parties.

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48. In the event that NNI elects to adjust the parameters of the aforementioned Affordability Programs and the parties disagree about whether the change(s) are inconsistent with the requirements of paragraph 20, the parties will promptly meet and confer in an attempt to resolve their dispute.

49. If the OAG believes that NNI has violated a provision of this Agreement, prior to taking legal action to enforce this Agreement as a result of the alleged violation, the OAG shall notify NNI in writing, identifying the alleged violation and the provision of this Agreement in question. NNI shall have thirty (30) days (the "Cure Period") from receipt of the written notice to cure the alleged violation, provide the OAG with a plan for curing any alleged violation promptly, or explain why the alleged violation is not an actual violation, and, where relevant, provide the OAG with a detailed written explanation of the corrective actions taken. In the event an actual violation has not been cured within the Cure Period, NNI shall be in breach of this Agreement. NNI shall not, however, be entitled to notice and an opportunity to cure an alleged violation if the OAG determines in good faith that a threat to the health, safety or welfare of the public requires immediate action.

50. To seek a modification of this Agreement for any reason, NNI shall make a written request for such modification. The OAG will respond to any such request within 45 days and give any such request reasonable consideration. Changed conditions, federal or state legislative or regulatory action, or any other circumstance that materially alters the marketplace for insulin or the terms on which insulin can or must be sold may properly serve as the basis for a request for modification of this Agreement.

51. This Agreement may not be amended except by an instrument in writing signed on behalf of the Parties to this Agreement.

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52. In the event that any one or more of the provisions contained in this Agreement shall for any reason be held by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement.

53. NNI acknowledges that it has entered this Agreement freely and voluntarily and upon due deliberation with the advice of counsel.

54. This Agreement shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

55. The Agreement and all its terms shall be construed as if mutually drafted with no presumption of any type against any party that may be found to have been the drafter.

56. This Agreement may be executed in multiple counterparts by the parties hereto. All counterparts so executed shall constitute one agreement binding upon all parties, notwithstanding that all parties are not signatories to the original or the same counterpart. Each counterpart shall be deemed an original to this Agreement, all of which shall constitute one agreement to be valid as of the Effective Date of this Agreement. For purposes of this Agreement, copies of signatures shall be treated the same as originals. Documents executed, scanned and transmitted electronically and electronic signatures shall be deemed original signatures for purposes of this Agreement and all matters related thereto, with such scanned and electronic signatures having the same legal effect as original signatures.

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Date: 9/8/23

LETITIA JAMES
Attorney General of the State of New York
28 Liberty Street
New York, NY 10005

By: Jane M. Azia

Jane M. Azia, Bureau Chief
Kate Matuschak, Assistant Attorney General
Consumer Frauds and Protection Bureau

Amy McFarlane, Deputy Bureau Chief
Antitrust Bureau

Steven J. Glassman
Special Counsel
Economic Justice Division

Date: August 3, 2023

NOVO NORDISK INC.

By:  Marc Fishman

Marc E. Fishman
Vice President, Chief Litigation Counsel