

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

STATE OF MINNESOTA, BY ITS
ATTORNEY GENERAL, KEITH ELLISON,

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC, NOVO
NORDISK INC., AND ELI NOVO NORDISK
AND CO.,

Defendants.

Civil Action No.: 18-cv-14999-BRM-RLS

**SETTLEMENT AGREEMENT,
RELEASE, AND ORDER**

WHEREAS, Plaintiff, State of Minnesota, by its Attorney General Keith Ellison (the “State” or “Attorney General”) filed a Complaint on October 16, 2018, in the United States District Court for the District of New Jersey, Civil Action 18-cv-14999, and filed a Second Amended Complaint on April 21, 2020 (the “Action”) against Novo Nordisk Inc. (“NNI”), among other defendants, asserting claims relating to NNI’s insulin products;

WHEREAS, NNI’s May 25, 2021 Answer and Affirmative Defenses to the Second Amended Complaint denied the State’s allegations;

WHEREAS, the State and NNI desire to resolve the Action by this Settlement Agreement, Release, and Order (the “Agreement”) containing the relief agreed to by the State and NNI, whether acting through its respective directors, officers, employees, representatives, agents, affiliates, and/or subsidiaries (the “Parties”); and

WHEREAS, to address access and affordability concerns, NNI has implemented affordability programs that provide free and discounted insulin products to consumers. Under one such program, for more than two decades, NNI has made charitable contributions of free

insulin products, which are provided to patients with financial need through its Patient Assistance Program;

WHEREAS, consistent with NNI's charitable intent of providing free products to patients in need, NNI intends to continue its Patient Assistance Program and provide its products to patients; and

NOW, THEREFORE, the Parties agree to the following terms and conditions:

DEFINITIONS

1. For the purposes of this Agreement, the definitions in paragraphs 2 through 15 apply.

2. "Affordability Solution" means the program NNI provides pursuant to paragraph 17 of this Agreement, which is currently called NNI's MyInsulinRx Program.

3. "Affordability Solution Website" means the web page or set of web pages maintained by NNI to disseminate information about its Affordability Solution described in paragraph 17, which, as of the Effective Date of this Agreement, was accessible at www.novocare.com.

4. "BIN" refers to the Bank Identification Number typically associated with a health insurance provider 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. "Biosimilar" means a biological product that the U.S. Food & Drug Administration (FDA) has approved as biosimilar to or interchangeable with a reference insulin product pursuant to a biologics license application submitted under section 351(k) of the Public Health Service Act.

6. “Cash-Paying Customer” refers to any Minnesota resident filling a prescription for an NNI Insulin Product at a pharmacy located in Minnesota where the prescription is not submitted for payment to or processed through any applicable Health Coverage, regardless of whether or not the Minnesota resident has Health Coverage, except a “Cash-Paying Customer” does not include Minnesota residents who receive Health Coverage through a Government Health Care Program.

7. “Covered Conduct” means any conduct, practices, acts, statements, disclosures, representations, or omissions occurring up to and including the Effective Date of this Agreement made by the NNI Released Parties in connection with sale of, purchase of, pricing of, rebates paid for, or contracting related to the NNI Insulin Products, whether alleged in the Second Amended Complaint or otherwise part of the Action brought by the State, known or unknown.

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

9. “Government Health Care Program” means any (i) "federal health care program" as that term is defined in 42 U.S.C. § 1320a-7b(f), including but not limited to Medicare, Medicaid, the United States Veterans Administration, the Department of Defense, TRICARE, and certain employer sponsored group waver health plans (EGWPs) or government-subsidized prescription drug benefit programs for Medicare eligible patients; and (ii) any State-funded or sponsored healthcare program, including but not limited to “state health care programs” as that term is defined in 42 U.S.C. § 1320a-7(h).

10. “Health Coverage” means any form of prescription drug coverage provided by a commercial health insurer, health maintenance organization, employer-sponsored health plan, or

other coverage provided by commercial or private payers or by any state or federal Government Health Care program.

11. “Insulin Product” means those branded insulin products that NNI currently markets—and continues to market while this agreement remains in effect—in the U.S. under the brand names NovoLog®, Tresiba®, Fiasp®, and Novolin®, regardless of formulation or delivery method. For the avoidance of doubt, nothing in this Agreement obligates NNI to continue to sell or market any particular Insulin Product.

12. “Monthly Prescription” means up to 3 vials or 2 packs of pens (up to 35mL) of NNI Insulin Products.

13. “Patient Assistance Program” means the NNI program that provides insulin at no cost to patients: (a) who are U.S. citizens or permanent residents; (b) who do not have insurance or who are enrolled in a Medicare Part D plan; (c) whose annual household income is at or below 400% of the federal poverty level, and (d) who are not enrolled in, nor qualify for any other federal, state, or government program such as Medicaid, Low Income Subsidy, or Veterans Affairs (VA) Benefits.

14. “Released Parties” means NNI, and its affiliates, divisions, parents, subsidiaries, assigns, and successors, and each of the foregoing’s past and present officers, directors, employees, representatives, and agents.

15. “Third-Party Messaging Company” means a company that provides messaging services to pharmacies in its network, including but not limited to, Change Healthcare’s eRx or RelayHealth.

NO ADMISSION OF LIABILITY

16. NNI has denied, and continues to deny, any wrongdoing, violation, or legal liability arising from any of the facts or conduct alleged in this Action. Neither this Agreement nor any settlement-related document is an admission of any wrongdoing, violation, or legal liability for any purpose, nor do the parties intend this Agreement to constitute evidence of any liability or unlawful conduct by NNI.

TERMS

17. NNI shall make available to Cash-Paying Customers, who present at the pharmacy with a valid prescription for NNI Insulin Products, the option to pay no more than \$35—or no more than the lowest applicable statutory cap under federal or Minnesota law for all commercially insured insulin users, whichever is lower—for the Cash-Paying Customer's Monthly Prescription. For the avoidance of doubt, to the extent that any federal or Minnesota law would reduce a Minnesota resident's out-of-pocket costs for an NNI Insulin Product to less than \$35 for a Monthly Prescription, this Agreement does not prevent that Minnesota resident from obtaining an NNI Insulin Product at that lower out-of-pocket cost pursuant to that law, as applicable.

18. NNI shall continue to make the option in Paragraph 17 available to Cash-Paying Customers in a format that is at least as accessible as the format utilized at novocare.com as of the Effective Date of this Agreement.

19. NNI's Affordability Solution Website shall have a feature that allows Cash-Paying Customers to receive electronically any coupon, co-payment card, or other documentation that they must present to a pharmacy for purposes of utilizing the Affordability Solution described in paragraph 17. NNI shall have representatives available either via telephone

or live chat feature on its Affordability Solution Website (or both), during regular business hours, who can communicate in Spanish, Hmong, and Somali.

20. For Minnesota 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 Government Health Care Program with prescription drug coverage, NNI shall continue to offer insulin at no cost in accordance with the terms of its Patient Assistance Program.

21. Within 60 days of the Effective Date, NNI shall enter into contract(s) with one or more Third-Party Messaging Companies to implement the following program, designed to assist Cash-Paying Customers who do not initially present with documentation regarding the Affordability Solution described in paragraph 17 with quickly obtaining the Affordability Solution described in paragraph 17 at the point of sale at pharmacies, subject to the terms of eligibility for the Affordability Solution:

- a. If a pharmacist at a pharmacy that allows the messaging described herein processes a Cash-Paying Customer's prescription for an NNI Insulin Product to its regular cash BIN, the Third-Party Messaging Company 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-Paying Customer's use NNI's Affordability Solution described in paragraph 17 by utilizing (or directing the Cash-Paying Customer to utilize) a specified link to NNI's Affordability Solution Website or a specified toll free number. If feasible, such messaging shall indicate that the consumer may be eligible for substantially discounted NNI Insulin Products.

- b. Upon receiving a Cash-Paying Customer's request to use its insulin Affordability Solution described in paragraph 17 at a pharmacy that allows the messaging described herein, NNI shall determine the Cash-Paying Customer's eligibility according to the terms of its Affordability Solution. NNI shall make eligibility determinations based on information received from the Cash-Paying Customer or pharmacy as promptly as possible, so as to enable the Cash-Paying Customer's access to NNI Insulin Products in accordance with the terms of the Affordability Solution described in paragraph 17. Upon a determination of eligibility, NNI shall immediately take steps to supply the pharmacist or eligible Cash-Paying Customer with an appropriate coupon, voucher, or other notification that includes a BIN that the pharmacy will submit for adjudication of the prescription.
- c. To the extent necessary to enable pharmacists to assist Cash-Paying Customers' use of NNI's Affordability Solution described in paragraph 17 in connection with the messaging described herein, NNI shall make reasonable modifications to its existing processes (for example, any additional training of call center employees).
- d. To the extent necessary to execute this program, NNI shall make reasonable modifications to its Affordability Solution Website and educate its call center employees to enable prompt pharmacist-assisted eligibility determinations for its Affordability Solution described in paragraph 17, and to comply with the foregoing provisions.

22. Beginning after NNI's first full calendar quarter after implementation of the messaging program and continuing for a period of three years thereafter, NNI shall submit to the Attorney General, no later than 45 days after the conclusion of the quarter, a report describing for

the prior quarter, with respect to Minnesota pharmacies, the following information, to the extent that such data is reasonably available, including from the Third-Party Messaging Company:

- a. Number of pharmacies that are participating in the messaging program described above in Paragraph 21 (“the Messaging Program”);
- b. 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 NNI’s Affordability Solution described in paragraph 17 and self-identify to NNI as not having Health Coverage;
- d. Representative samples of the informational materials regarding NNI’s Affordability Solution described in paragraph 17 approved to be provided to providers, pharmacies, and consumers; and
- e. The publicly reported list price for NNI’s Insulin Products as of the beginning of the relevant quarter.

23. NNI shall maintain for at least three years all underlying documentation and data supporting the reports described in Paragraph 22, and shall furnish this documentation and data to the Attorney General upon request within 14 days of such request.

24. NNI shall report any material changes to the terms and conditions of its Affordability Solution described in paragraph 17 which are applicable to Cash-Paying Customers within 30 days of the implementation of those changes.

25. In any case where the circumstances warrant, the Attorney General may require NNI to submit an interim report upon 30 days’ notice containing the items specified in Paragraph 22 of this Agreement.

RELEASE

26. Upon the execution of this Agreement, the NNI Released Parties are hereby released and forever discharged from any and all claims, causes of action, or requests for relief of any kind arising from, connected with, or related to the Covered Conduct that the State and any of its departments, agencies, divisions, boards, or commissions, including the Attorney General, now has or may hereafter have against the NNI Released Parties, including claims for damages, restitution, disgorgement, injunctive or other equitable relief, fines, costs, expenses, fees (including attorney's fees), and penalties pursuant to 18 U.S.C. § 1962, Minnesota or federal antitrust laws, the Minnesota or federal False Claims Act, Minnesota Statutes §§ 325D.43-48, 325F.67, and 325F.68-.694, or under other state or federal statutory, regulatory, or common law theories, in law or in equity, such as unfair, deceptive, or fraudulent trade practices, fraud, negligence, strict liability, warranty or breach thereof, willful or reckless misconduct, or unjust enrichment, including any and all claims and allegations that were or could have been asserted in the Action.

27. The State, through this Agreement, reserves, and does not settle, release, or resolve any of the following claims, rights, and remedies against the NNI Released Parties:

- Any claims arising under state tax laws;
- Any claims for the violation of securities laws;
- Any criminal liability;
- Any civil or regulatory claims unrelated to the Covered Conduct;
- Any civil or regulatory claims involving conduct required or prohibited by Minnesota Statutes Chapter 151, including Minnesota Statutes section 151.74; provided, however, that such reservation does not include claims under Minn. Stat. § 151.061 or disciplinary

action under Minn. Stat. § 151.071 subds. 2(6), 2(9), 2(17), or 2(21) related to the Covered Conduct;

- Any civil or regulatory claims involving the reporting required by Minnesota Statutes section 62J.84;
- Any claims for breach of contract that the administrator of MMCAP Infuse or a member of MMCAP Infuse could assert regarding the agreements MMS2100564, MMS2100563, MMS2000324, MMS2100562, MMS2100561, MMS2100560, MMS16016, MMS11099, and MMS27096 between the Minnesota Department of Administration and the NNI Released Parties; provided, however, that such reservation does not include claims related to the allegations in the Second Amended Complaint;
- Any claims involving Medicaid drug rebates; provided, however, that such reservation does not include claims related to the allegations in the Second Amended Complaint;
- Any claims of any other person or entity involving any private causes of action, claims, and remedies brought by a private party, including, but not limited to, private causes of action, claims, or remedies provided for under Minn. Stat. § 8.31 subd. 3a; and
- Any action to enforce this Agreement and subsequent, related orders or judgments.

The NNI Released Parties reserve, and this Agreement does not settle, release, or resolve, and is without prejudice to, all defenses with respect to the above claims, rights, and remedies listed in this paragraph.

28. Nothing in this Agreement waives any defenses that may be raised in response to any claims, causes of action, or requests for relief of any kind brought by or on behalf of any NNI Released Party. For the avoidance of doubt, nothing in this paragraph is intended to narrow or alter the scope of the release in Paragraph 26, which includes, among other things, a release

from claims, counterclaims, and third-party claims arising from, connected with, or related to the Covered Conduct that could be brought by the State against the NNI Released Parties.

29. The release in Paragraph 26 of this Agreement does not in any way release claims against any of the defendants in the Action aside from NNI.

30. In consideration of the covenants set forth herein, within ten (10) days of the Effective Date, or within ten (10) days of approval and signature by the Court, whichever is later, the Attorney General shall file a Dismissal with Prejudice, pursuant to which the Attorney General shall dismiss with prejudice all of its respective claims against NNI in the Action, with each party to bear its own costs, expenses, and attorneys' fees.

DISPUTE RESOLUTION

31. The Parties agree that United States District Court for the District of New Jersey shall retain jurisdiction over all disputes regarding this Agreement. The Parties consent to jurisdiction by this Court to hear any Motion seeking to enforce, modify, or interpret this Agreement. Any such Motion shall be filed in accordance with Local Civil Rule 7.1 of the Local Civil and Criminal Rules of the United States District Court for the District of New Jersey.

32. To the extent that the Attorney General has good cause to believe that NNI has not complied with any provision of this Agreement, the Attorney General shall notify NNI in writing of the specific objection, identify with particularity the provisions of this Agreement that have allegedly not been complied with, and give NNI 30 business days to respond to the notification.

33. Upon receipt of written notice from the Attorney General, NNI shall provide a good-faith written response to the Attorney General containing either a statement explaining why NNI believes it is in compliance with the Agreement or a detailed explanation of how the alleged

violation occurred and a statement explaining how and when NNI intends to remedy the alleged violation. The Attorney General may not take any action during the 30-day response period. Nothing shall prevent the Attorney General from agreeing in writing to provide NNI with additional time to respond to the notice.

34. The provisions of this Agreement shall be construed in accordance with the laws of the State of Minnesota.

GENERAL TERMS

35. Unless otherwise specified within this Agreement, NNI's obligations under this Agreement shall continue for a period of five years after the Effective Date. Nothing in this Agreement shall relieve NNI of other obligations imposed by any applicable state or federal law or regulation or other applicable law.

36. This Agreement in no way alters any contracts or agreements NNI has with any Minnesota governmental entity, and NNI will not seek to modify or change any contractual terms made with a Minnesota governmental entity in retaliation for the underlying lawsuit or as a result of the execution of this Agreement.

37. The Parties acknowledge that certain performance obligations involving third parties may be outside of the Parties' control, including the actions of Third-Party Messaging Companies, wholesalers, pharmacies, individual pharmacists, health care providers, consumers, and other actors in the drug supply chain. In the event that NNI believes that any third party is interfering with the purpose of the Agreement or obstructing, impairing, or delaying NNI's ability to comply with its obligations under this 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.

38. Neither of the Parties shall have any responsibility, financial obligation, or liability for the failure of:

- a. any Third-Party Messaging Company to convey the Messaging Program to participating pharmacies;
- b. any participating pharmacy to relay the Messaging Program to a Cash-Paying Customer;
- c. any pharmacy that declines to process prescriptions through the Affordability Solution described in paragraph 17 or participate in the Messaging Program;
- d. any Cash-Paying Customers to enroll in the Affordability Solution described in paragraph 17 because they declined to act on the Messaging Program; or
- e. any Cash-Paying Customers to receive, accept, or use NNI Insulin Products.

39. Notwithstanding any other provision of this Agreement, NNI shall have the right to restrict access to the Affordability Solution described in paragraph 17 for a particular NNI Insulin Product if any federal or State law would reduce a Cash-Paying Customer's out-of-pocket costs for the NNI Insulin Product to \$35 or less for a Monthly Prescription of that NNI Insulin Product. NNI may restrict access to the Affordability Solution described in paragraph 17 in this manner for only the Cash-Paying Customers who would benefit from the federal or State law described in this paragraph. NNI may only restrict eligibility to the Affordability Solution described in paragraph 17 under this paragraph so long as the federal or State law is in effect, and eligibility may not be restricted under this Agreement if the federal or State law is enjoined, stricken, repealed, or amended in a manner that makes the law less favorable to Cash-Paying Customers than the terms of this Agreement.

40. Notwithstanding any other provision of this Agreement, NNI shall have the right to restrict access to the Affordability Solution described in paragraph 17 for a particular NNI Insulin Product if the WAC or list price for the particular NNI Insulin Product falls and remains below \$35 per Monthly Prescription for at least four consecutive calendar quarters. NNI may only restrict eligibility to the Affordability Solution described in paragraph 17 under this paragraph so long as the WAC or list price for the particular NNI Insulin Product for which the restriction is enacted remains below \$35 per Monthly Prescription.

41. In the event that Minnesota or the federal government secure an agreement or order requiring, or any federal or State law requires, a pharmacy benefits manager or payor to make a monthly supply of a covered NNI Insulin Product available to Minnesota residents for \$35 or less out-of-pocket under commercial insurance, NNI shall have no obligation to make its Affordability Solution described in paragraph 17 available to any Cash-Paying Customer who has access to that particular NNI Insulin Product under such commercial insurance.

42. To seek a modification of this Agreement, NNI shall make a written request for such modification to the Attorney General. The Attorney General will respond to any such request within 60 days, and that response may be a request for additional information. NNI will not unreasonably withhold additional information, and the Attorney General will not unreasonably withhold consent to modify this Agreement in light of federal or state legislative or regulatory action, or any other conditions that would make performance impractical or impossible. This Agreement may not be amended except by an instrument in writing signed on behalf of the Parties to this Agreement.

43. 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.

44. 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.

45. Any failure by any Party to this Agreement to insist upon the strict performance by another Party of any provision of this Agreement shall not be deemed a waiver of such provision.

46. Each person signing this Agreement represents that such person has the authority to bind their respective Party to this Agreement.

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

48. 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. 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.

49. The failure of a party to exercise any rights under this Agreement shall not be deemed to be a waiver of any right or any future rights.

50. Nothing in this Agreement shall be construed to limit the power or authority of the State of Minnesota or the Attorney General except as expressly set forth herein.

51. This Agreement constitutes the full and complete terms of the agreement entered into by the Parties hereto. The Parties agree that (1) this Agreement, prior versions of this Agreement, and any communications or documents relating to this Agreement, are protected from disclosure under Minn. R. Evid. 408 and Federal Rule of Evidence 408; and (2) this Agreement, prior versions of this Agreement, and any communications or documents relating to this Agreement, may not be introduced in any action for any purpose whatsoever, other than for purposes of enforcing this Agreement.

52. Notices or communications required by or related to this Agreement must be sent via certified mail or emailed to the following persons, or any person subsequently designated by the parties to this Agreement to receive such notices:

If to NNI, to:

Marc Fishman
VP, Deputy General Counsel – Head of Litigation North America
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
(609) 786-5247
mrfh@novonordisk.com

or in his absence, to the person holding the title of VP, Deputy General Counsel – Head of Litigation North America.

If to the Attorney General, to:

Noah Lewellen
Assistant Attorney General
Office of the Minnesota Attorney General
445 Minnesota Street, Suite 1400
St. Paul, MN 55101
noah.lewellen@ag.state.mn.us

If mail or email is returned or indicated as undeliverable, notice on the Attorney General shall be made to the Manager or Deputy of the AGO's Consumer, Wage, and Antitrust Division, or any successor division that is responsible for civil enforcement of consumer-protection laws.

53. On or before executing this Agreement, NNI shall provide the Attorney General with NNI's taxpayer identification number (TIN) or social security number. NNI shall cooperate in the Attorney General's completion of IRS Form 1098-F by providing the Attorney General with any additional information requested by the Attorney General regarding that form.

Dated: January 23, 2025

KEITH ELLISON
Attorney General
State of Minnesota

JAMES W. CANADAY
Deputy Attorney General

JESSICA WHITNEY
Deputy Attorney General

By: s/ Noah Lewellen

NOAH LEWELLEN
Assistant Attorney General


JASON PLEGGENKUHLE
Assistant Attorney General

ALEX BALDWIN
Assistant Attorney General

JUSTIN MOOR
Assistant Attorney General

Dated: December 5, 2024

NOVO NORDISK INC.

By: 
65E26D7EADB0461...

ULRICH CHRISTIAN OTTE
Senior Vice President
Novo Nordisk Inc.

ORDER

Based upon the foregoing Agreement, it is SO ORDERED.

Date: _____

THE HONORABLE
BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE

**Certificate Of Completion**

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Signatures: 1

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Candece Duclos

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Novo Allé, 2880 Bagsværd

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Copenhagen, 2300

Time Zone: (UTC+01:00) Brussels, Copenhagen, Madrid, Paris

cudy@novonordisk.com

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Ulrich Christian Otte

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UCO@novonordisk.com



Viewed: 12/5/2024 6:58:44 PM

SVP Finance & Operations

Novo Nordisk Inc

Signature Adoption: Drawn on Device

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Electronic Record and Signature Disclosure:

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Company Name: Novo Nordisk A/S

In Person Signer Events**Signature****Timestamp****Editor Delivery Events****Status****Timestamp****Agent Delivery Events****Status****Timestamp****Intermediary Delivery Events****Status****Timestamp****Certified Delivery Events****Status****Timestamp****Carbon Copy Events****Status****Timestamp****Witness Events****Signature****Timestamp****Notary Events****Signature****Timestamp****Envelope Summary Events****Status****Timestamps**

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