

FOR SETTLEMENT PURPOSES ONLY

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

In the Matter of

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

Sanofi-Aventis U.S. LLC,

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 the insulin pricing practices of Sanofi-Aventis U.S. LLC (“Sanofi,” as defined more fully below). This Settlement Agreement (“Agreement”) contains the findings of the OAG’s investigation as well as the relief agreed to by the OAG and Sanofi, whether acting through its respective directors, officers, employees, representatives, agents, and/or subsidiaries (collectively, the “Parties”).

OAG Findings

1. Currently, approximately 7.4 million Americans with diabetes rely on insulin.¹ In New York, approximately 1.6 million, or 10.5 percent, of adult New York residents have

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>.

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diabetes.² A recent Community Health Survey estimated that 464,000 of them are insulin-dependent.³ According to the Centers for Disease Control, 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, with 1.4 million new diagnoses in 2019.^{5 6}

2. Diabetes has disproportionately affected poor New Yorkers. 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.^{7 8} In 2019, 16.1% of adults in New York with diabetes had an annual household income of less than \$25,000 compared to only 6.3% of adults with an annual household income of \$50,000 and greater.⁹

3. Over the past two decades, as the numbers of people diagnosed with diabetes has increased, the cost of insulin has increased significantly. From 2002 to 2013, average list prices

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 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>.

⁶ CDC, *National Diabetes Statistics Report, 2020*, available at <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>.

⁷ See <https://www1.nyc.gov/assets/doh/downloads/pdf/survey/survey-2009diabetes.pdf>.

⁸ 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>.

⁹ CDC, *BRFSS Brief, 2019*, available at https://www.health.ny.gov/statistics/brfss/reports/docs/2021-21_brfss_diabetes.pdf.

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for analog insulins nearly tripled from \$4.34/ml to \$12.92/ml.¹⁰ Between 2014 and 2018, the mean list price for 32 analog insulin products grew by 40.1%, from \$19.60 to \$27.45.¹¹ Certain categories of consumers, including those with high deductible insurance and those who are uninsured, have struggled to afford the drug. One study found that 25% of insulin-dependent individuals in the United States have rationed the drug due to its cost.¹²

4. A 2018 study estimated that manufacturing costs for biosimilar versions of regular human insulin (RHI) would range from \$48-71, and the costs for most insulin analogs would range from \$78-133 per person per year.¹³ A separate analysis of insulin pricing found that annual spending per person with Type 1 diabetes on insulin was \$2,864 in 2012, which increased to \$5,705 in 2016.¹⁴ According to this analysis, during this time period, the average insulin point-of-sale prices nearly doubled, with RHI increasing between 93-134%, and insulin analogs increasing by 69-138%.¹⁴

5. Drug manufacturers set list prices that are a factor in determining the prices at which health plans (and uninsured consumers) reimburse pharmacies for prescriptions. Pharmacy benefit managers (“PBMs”), which represent health insurance plans, negotiate with

¹⁰ Hua X., Carvalho N., Tew M., Huang E. S., Herman W. H., 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.

¹¹ 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.

¹² 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>.

¹³ 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>.

¹⁴ Binick, 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>.

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drug manufacturers and pharmacies on behalf of the health insurance plans they represent. In order to obtain favorable placement on a health plan's formulary relative to other manufacturers' products, PBMs may require that manufacturers offer to rebate a portion of an insulin's list price to PBMs. When manufacturers increase list prices, they may be able to offer larger rebates to PBMs. According to a 2019 study, the manufacturers' net revenues have decreased as PBMs' and other distribution intermediaries' rebate demands grew, constituting an increasing share of insulin expenditures between 2014 and 2018.¹⁵ In addition, PBMs and other distribution intermediaries demand administrative fees from manufacturers that are keyed to the list prices of analog insulins and other drugs.

6. Certain categories of consumers are less likely to benefit from discounted prices negotiated by PBMs and/or health insurance plans, and more likely to pay an amount related to the list price than others. Consumers with high deductible health plans, which require them to pay a percentage of the cost of the product until they reach a certain monetary threshold, are likely to pay an amount related to the list price for a certain portion of the year. Consumers without insurance are also likely to pay an amount linked to the list price.

7. To address access and affordability concerns, Sanofi has implemented patient support programs that provide discounted or free insulin products to consumers enrolled in those programs. However, many consumers who are eligible for the programs are not enrolled in them. This is due, in part, to a lack of awareness of their eligibility for these programs.

8. Sanofi neither admits nor denies the OAG's findings, reflected in Paragraphs 1 through 7 above.

¹⁵ Van Nuys et al., *supra* note 11.

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9. The OAG finds the relief and agreements contained in this Agreement appropriate and in the public interest. Therefore, the OAG is willing to accept this Agreement pursuant to Executive Law § 63(15) in lieu of commencing a statutory proceeding for violations of Executive Law § 63(12) or GBL Article 22-A, §§ 349 and 350 based on any allegations related to Sanofi's insulin pricing practices or the OAG's findings in Paragraphs 1 through 7 above.

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

Definitions

10. "Affordability Programs" means Sanofi's Insulin ValYou Savings Program and Patient Connection Program as defined herein.

11. "Affordability Program website" means www.insulinsvalyou.com and the "Savings" tab on the individual web pages for Sanofi's Insulin Products.

12. "BIN" refers to the Bank Identification Number associated with a particular payor, health plan, or patient assistance program, that is used to route and process pharmacy claims.

13. "Cash Code" refers to the internal code (whether a BIN, U&C, or other code) that a Participating Pharmacy uses to process Cash Patient pharmacy claims.

14. "Cash Patient" refers to any individual without Prescription Medication Insurance who seeks to fill a prescription for one or more of the Sanofi Insulin Products at a pharmacy in New York.

15. "Clear and Conspicuous" (including "Clearly and Conspicuously") means that a 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

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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.

16. “Enrollment Message” means a message for which Sanofi will contract with Third-Party Messaging Companies to inform Participating Pharmacies about the Insulin Affordability Programs.

17. “Health Care Provider” or “HCP” means any health care professional or facility licensed to provide health care diagnostic and treatment services and to prescribe medications.

18. “Insulin Products” means those Sanofi insulin products that Sanofi sells under the brands Lantus®, Toujeo®, Apidra®, and Admelog®, and any biosimilar versions of those insulin products that Sanofi may market in the United States, while this Agreement is in effect.

19. “Insulin ValYou Savings Program” means the Sanofi affordability solution for patients without Prescription Medication Insurance who affirm (directly or with the assistance of Participating Pharmacies) that they (a) are over the age of 18 and resident of the United States, Puerto Rico, Guam, or the U.S. Virgin Islands and (b) do not have Prescription Medication Insurance (as that term is defined herein). Cash Patients taking Insulin Products who enroll in the program may receive one or multiple Sanofi insulins for a total of \$35 for a 30-day supply so long as they fill the prescriptions together and at the same time each month.

20. “Participating Pharmacy” means any pharmacy in the Third-Party Messaging Company’s network that has opted to receive the Enrollment Message.

21. “Patient Connection Program” or “PCP” means the Sanofi affordability program that provides the Insulin Products (among others) at no cost to patients (a) who are residents of the United States or one of its territories and under the care of a Health Care Provider authorized to prescribe, dispense, and administer medicine in the United States or one of its territories;

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(b) who do not have Prescription Medication Insurance, or coverage for or access to the Insulin Products under any commercial Prescription Medication Insurance, or who are enrolled in a Medicare Part D plan; (c) whose annual household income does not exceed 400% of the current Federal Poverty Level; (d) who are not eligible for Medicaid; and (e) who successfully complete the program application with the assistance of their Health Care Provider.

22. "Prescription Medication Insurance" means any form of insurance provided by commercial or private insurers, or by Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs.

23. "Sanofi" means Sanofi-Aventis U.S. LLC, the sole Sanofi entity authorized and licensed to market and sell the Insulin Products in the United States, and shall include any other Sanofi entity subsequently authorized and/or licensed to market and sell the Insulin Products in the United States.

24. "Third-Party Messaging Company" means Change Healthcare, RelayHealth, or any other company, affiliate, or subsidiary that provides messaging services to pharmacies in a defined network.

25. "U&C Code" means the usual and customary code that a Participating Pharmacy may use to process Cash Patient pharmacy claims.

26. "Wholesale Acquisition Cost" or "WAC" means Sanofi's list price for the Insulin Products to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.

27. "Effective Date" means the date upon which this Agreement has been fully executed by all of the signatories below.

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Prospective Relief

Continuing Affordability Solutions

28. Sanofi shall maintain the Affordability Programs for each Insulin Product on terms and conditions at least as favorable to Cash Patients as the terms and conditions that apply to the programs applicable to that Insulin Product as of the Effective Date of this Agreement (as described in the definitions of the Insulin ValYou Savings Program and the Patient Connection Program above).

Pharmacy-Assisted Rapid Affordability Determinations

29. Within 60 days of the Effective Date, Sanofi shall implement the following program, designed to inform persons who do not have Prescription Medication Insurance about the Insulin Affordability Programs:

a. If a Participating Pharmacy processes a Cash Patient's prescription for one or more of the Insulin Products using its regular Cash Code, the Third-Party Messaging Company with which Sanofi has contracted will provide the pharmacy with the Enrollment Message, which shall advise the Participating Pharmacy: (i) that Cash Patients need not pay more than \$35 a month for the Insulin Products; (ii) that the pharmacist can help the Cash Patient learn about the Affordability Programs and apply for enrollment in the Insulins ValYou Savings Program by visiting www.insulinsvalyou.com or calling 855-984-6302 (or directing the Cash Patient to do so); and (iii) that low-income patients should ask their HCPs about free insulins from the Patient Connection Program.

b. Upon receiving a Cash Patient's affirmation that he or she meets the eligibility criteria for the Insulin ValYou Savings Program, Sanofi shall promptly (generally within a matter of minutes) provide the Cash Patient (or the pharmacist facilitating the affirmation) with the BIN

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for the Insulin ValYou Savings Program, as well as a patient-specific identification number to facilitate adjudication of a claim under the Insulin ValYou Savings Program.

c. If necessary to enable pharmacists to assist in the enrollment of Cash Customers, Sanofi shall make reasonable modifications to its existing application process (for example, by implementing any additional training necessary for call center operators).

d. If necessary to execute this program, Sanofi shall make reasonable modifications to www.insulinsvalyou.com, as well as on the "Savings" tab on the individual web pages for its Insulin Products, and educate its call center employees to facilitate prompt pharmacist-assisted patient affirmations for the Insulin ValYou Savings Program and to comply with the foregoing provisions.

Outreach

30. Sanofi shall disclose its insulin affordability offerings, and provide information regarding how to apply for these offerings, as set forth herein:

a. Clearly and conspicuously on www.insulinsvalyou.com and the "Savings" tab on the product pages on Sanofi's website for each of the Insulin Products; and

b. In any informational materials provided to pharmacies and healthcare providers.

31. Sanofi shall promptly respond to any requests for information or other inquiries from the Pharmacists Society of the State of New York, the New York Board of Pharmacy, or from New York pharmacists about the Affordability Programs. Specifically, Sanofi shall provide timely information about the Affordability Programs with the goal of promoting pharmacist knowledge, and patient utilization, of those programs.

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Affordability Program Website Accessibility

32. Sanofi's affordability program websites shall continue to direct Cash Patients to an interactive interface allowing them to identify the savings programs for which they may be eligible, including the Insulins ValYou Savings Program and the Patient Connection Program. This tool shall be displayed on www.insulinsvalyou.com or on a page Clearly and Conspicuously identified on it (such as the savings pages for each of the Insulin Products). The interface shall direct consumers to the steps needed to access or apply for the program(s) for which they are eligible (e.g., an affirmation of eligibility for the Insulins ValYou Savings Program and a Clear and Conspicuous link to the program card that must be presented at the pharmacy, and an explanation of the steps necessary for low income patients to apply for free Insulin Products under the Patient Connection Program).

33. Sanofi's affordability program website shall have a feature for the Insulins ValYou Savings Program that allows consumers to access via email or text message, any coupon, co-payment card, or other documentation that they must present to a pharmacy.

34. Sanofi shall offer live support via telephone during regular business hours, for consumers who are using, or are seeking to use, the Affordability Programs. The telephone number shall be Clearly and Conspicuously displayed on www.insulinsvalyou.com and the savings pages for each of the Insulin Products.

35. Sanofi shall continue to make Spanish and Mandarin Chinese-speaking operators available to assist individuals needing translation assistance. Further, Sanofi shall modify www.insulinsvalyou.com and the savings pages for each of the Insulin Products to direct Spanish or Mandarin Chinese-speaking patients to call the toll-free telephone number for information about the Affordability Programs in Spanish and/or Mandarin Chinese.

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Reporting and Recordkeeping

36. Beginning four months after the Effective Date of this Agreement and continuing for a period of three years thereafter, Sanofi shall submit to the OAG, no later than 30 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, at a minimum:

- a. Number of times a message was sent via a Third-Party Messaging Company to a Participating Pharmacy in response to a pharmacist entering a Cash Code;
- b. Number of Cash Patients who enrolled in the Affordability Programs;
- c. Number of Cash Patients who enrolled in the Affordability Programs with the assistance of a pharmacist (to the extent that information is reasonably ascertainable);
- d. Total value of discounts provided to Cash Patients who enrolled in the Affordability Programs;
- e. Representative samples of any informational or sales materials distributed or disseminated to providers, pharmacies, and/or patients regarding the Affordability Programs; and
- f. The publicly reported WAC or list price for the Insulin Products or any biosimilar version thereof.

37. Sanofi shall maintain all underlying documentation and data supporting the reports described in Paragraph 36, for at least three years, and shall furnish this documentation and data to the OAG within 30 days of any request from the OAG for such documentation and data.

38. Sanofi shall also be obligated to report any changes to the Affordability Programs within 30 days of implementing them. In the event that the OAG believes that the changes

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would lessen the benefits provided to Cash Patients, the parties will promptly meet and confer in an attempt to address the OAG's concerns and resolve any dispute.

39. In any case where the circumstances warrant, the OAG may require Sanofi to submit an interim report of compliance upon 30 days' notice. Any such report shall include, at a minimum, all items specified in Paragraph 36.

Subsequent Proceedings

40. Sanofi 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 50, and agrees and acknowledges that in such event:

a. any statute of limitations or other time-related defenses are tolled from and after the Effective Date of this Agreement;

b. the OAG may use statements, documents or other materials produced or provided by Sanofi prior to or after the Effective Date of this Agreement; and

c. any civil action or proceeding must be adjudicated by the courts of the State of New York, and that Respondent irrevocably and unconditionally waives any objection based upon personal jurisdiction, inconvenient forum, or venue.

41. If a court of competent jurisdiction determines that Sanofi has violated the Agreement, Sanofi shall 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.

42. The OAG accepts this Agreement in lieu of commencing a proceeding and agrees not to file, commence, or pursue a statutory proceeding against Sanofi for violations of Executive

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Law § 63(12) or GBL Article 22-A, §§ 349 and 350 based on any allegations related to Sanofi's insulin pricing practices or on conduct described in the OAG's findings in Paragraphs 1 through 7 above that occurred prior to the Effective Date.

Effects of Agreement:

43. This Agreement shall constitute the entire, complete, and integrated agreement between the OAG and Sanofi and supersedes any and all prior and contemporaneous communications of the Parties in connection therewith. All terms of the Agreement are contractual and not mere recitals.

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

45. All terms and conditions of this Agreement shall continue in full force and effect on any Sanofi entity authorized and/or licensed to market and sell the Insulin Products in the United States after the Effective Date of this Agreement, and Sanofi shall include in any such successor, assignment or transfer agreement a provision that binds the successor, assignee or transferee to the terms of this Agreement. Sanofi-Aventis U.S. LLC may not assign, delegate, or otherwise transfer any of its rights or obligations under this Agreement to another Sanofi entity without the prior written consent of the OAG.

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

47. Any failure by the OAG to insist upon Sanofi's strict performance 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 Sanofi's strict performance of any and all of the provisions of this Agreement.

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Communications:

48. 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, followed by postage prepaid mail, and shall be addressed as follows:

If to Sanofi, to:

Julie McEvoy
Theresa Martin
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3867
jmcevoy@jonesday.com
tcoughlin@jonesday.com

or in their absence, to the person holding the title of Vice President, Associate General Counsel & Head, N.A. Litigation & Investigations at Sanofi-Aventis U.S. LLC, 55 Corporate Drive, Bridgewater, NJ 08807.

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.

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Representations and Warranties:

49. Unless a term limit for compliance is otherwise specified within this Agreement, Sanofi's obligations under this Agreement shall continue for a period of 5 years after the Effective Date. Nothing in this Agreement shall relieve Sanofi of other obligations imposed by any applicable state or federal law or regulation or other applicable law.

50. The OAG has agreed to the terms of this Agreement based on, among other things, the representations Sanofi and its counsel made to the OAG and the OAG's own factual investigation as set forth in Findings, Paragraphs 1 through 7 above. Sanofi 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 Sanofi or its counsel are later found to be inaccurate or misleading, this Agreement is voidable by the OAG in its sole discretion.

51. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Agreement has been made to or relied upon by Sanofi in entering this Agreement.

52. Sanofi represents and warrants that the terms and conditions of this Agreement are duly approved. Sanofi further represents and warrants that Susan A. Manardo is the Sanofi employee duly authorized to enter into this Agreement.

Third Parties

53. The parties acknowledge that certain of the undertakings set forth herein involve third parties that may be outside of the parties' control, including Health Care Providers, Third-Party Messaging Companies, and Participating Pharmacies. In the event that the OAG or Sanofi believes that any third party's action or inaction is interfering with the purpose of the Agreement,

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the parties will confer in good faith about steps that either or both may be able to take to encourage cooperation by the third party(ies).

54. Neither of the Parties shall have any responsibility, financial obligation, or liability for the failure of (a) any Third-Party Messaging Service to convey the Enrollment Message to Participating Pharmacies; (b) the Participating Pharmacy to relay the Enrollment Message to a Cash Patient; or (c) any Cash Patient to enroll in the Insulin Affordability Programs because he or she declined to receive or act on the Enrollment Message.

55. The actions described above shall constitute the extent and total of the Parties' obligations and shall remain in effect for the duration of this Agreement. The Parties shall have no other obligations to one another except as set forth herein.

Disputes

56. If the OAG believes that Sanofi 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 Sanofi and identify the alleged violation and the provision of this Agreement in question. Sanofi shall have thirty (30) days (the "Cure Period") to cure the alleged violation, or explain why the alleged violation is not an actual violation, and provide the OAG with a detailed written explanation of the corrective actions taken. In the event a violation has not been cured within the Cure Period, Sanofi shall be in breach of this Agreement. Sanofi shall not, however, be entitled to notice and an opportunity to cure an alleged violation on more than two occasions or if the OAG determines it is objectively reasonable that Sanofi's alleged violation of the Agreement is a threat to the health, safety or welfare of the public requires immediate action.

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57. Nothing contained herein shall be construed to limit the remedies available to the OAG for a breach of this Agreement or in the event that Sanofi violates the Agreement after the Effective Date.

Privilege and Confidentiality

58. Nothing in this Agreement, settlement, or the negotiations or proceedings relating to the foregoing is intended to or shall be deemed to constitute a waiver of any applicable privilege or immunity including, without limitation, the attorney-client privilege, the joint defense privilege, or work product immunity.

General Principles

59. To seek a modification of this Agreement for any reason, Sanofi shall make a written request for such modification. The OAG will give any such request reasonable consideration.

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

61. 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, in the sole discretion of the OAG, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement.

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

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

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64. 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.

65. 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.

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

May 2
Date: ~~April 28~~, 2023

By: 
Kate Matuschak, Assistant Attorney General
Consumer Frauds and Protection Bureau

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Consumer Frauds and Protection Bureau

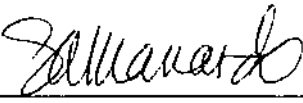
Amy McFarlane, Deputy Bureau Chief
Antitrust Bureau

Steven J. Glassman
Special Counsel
Economic Justice Division

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Sanofi-Aventis U.S. LLC

Date: April 28, 2023

By: 

Susan A. Manardo
Vice President, Associate General Counsel & Head,
N.A. Litigation & Investigations