

SETTLEMENT AGREEMENT

This Settlement Agreement (the “Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), (collectively, the “United States”), Biogen Inc. (“Biogen”), and Paul Nee (the “Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Biogen is a Delaware corporation with its principal office located in Cambridge, Massachusetts. Biogen manufactures and markets pharmaceutical products, including Avonex, and Tysabri, which are both indicated to treat Multiple Sclerosis (MS).

B. On or about February 3, 2017, Relator filed an action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Paul Nee v. Biogen Inc., et al.*, No. 17-cv-10192, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”).

C. The United States contends that Biogen caused the submission of claims for payment of Avonex and Tysabri to the Medicare program.

D. When a patient obtains a prescription drug covered by Medicare, the patient may be required to make a payment, which may take the form of a “copayment,” “coinsurance,” or “deductible” (collectively “co-pays”). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration – which includes money or any other item of value (such as a co-pay) – to induce Medicare beneficiaries to purchase, or their physicians to prescribe, the companies’ drugs.

E. The United States contends that it has certain civil claims, as specified below, against Biogen for engaging in the conduct below during the period from January 1, 2011, through December 31, 2013 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges:

Biogen used third-party foundations Chronic Disease Fund (“CDF”) and The Assistance Fund (“TAF”) as conduits to pay the copay obligations of Medicare patients taking Avonex and Tysabri. Medicare then subsequently paid these patients’ claims for Avonex and Tysabri.

With respect to Biogen’s payment of copays through CDF for Avonex patients in 2011, Biogen identified for its vendor, Advanced Care Scripts (“ACS”), Avonex Medicare beneficiaries whom Biogen could transfer from Biogen’s free drug program to CDF so that CDF could pay the Medicare copays for these patients and Biogen could receive Medicare revenue from the resulting Medicare claims for Avonex. In the first quarter of 2011, Biogen paid CDF and worked with ACS to transition those same patients to CDF. At Biogen’s direction, ACS then sent CDF “batch files” of applications for Medicare-eligible Avonex patients, and CDF (after receiving Biogen’s payment) subsequently approved most or all of those applications and covered the costs of those patients’ Medicare co-pays for Avonex. Medicare subsequently paid these patients’ claims for Avonex.

With respect to Biogen’s payment of copays through TAF for Tysabri patients in 2012, Biogen identified for ACS Tysabri Medicare beneficiaries whom Biogen could transfer from Biogen’s free drug program to TAF so that TAF could pay the Medicare copays for these patients and Biogen could receive Medicare revenue from the resulting Medicare claims for Tysabri. In the second and third quarters of 2012, Biogen paid TAF and worked with ACS to transition those same patients to TAF. At Biogen’s direction ACS then sent TAF “batch files” of

applications for Medicare-eligible Tysabri patients, and TAF (after receiving Biogen's payment) subsequently approved most or all of those applications and covered those patients' Medicare co-pays for Tysabri. Medicare subsequently paid these patients' claims for Tysabri.

With respect to Biogen's payment of copays through CDF for Tysabri patients in 2013, Biogen identified for ACS Tysabri Medicare beneficiaries who Biogen could transfer from Biogen's free drug program to CDF so that CDF could pay the Medicare copays for these patients and Biogen could receive Medicare revenue from the resulting Medicare claims for Tysabri. In the second and third quarters of 2013, Biogen paid CDF and worked with ACS to transition those same patients to CDF. At Biogen's direction, ACS then sent CDF "batch files" of Medicare-eligible Tysabri patients, and CDF (after receiving Biogen's payment) subsequently approved most or all of those applications and covered those patients' Medicare co-pays for Tysabri. Medicare subsequently paid these patients' claims for Tysabri.

The United States alleges that Biogen's payments to CDF in 2011, TAF in 2012 and CDF in 2013 referenced above were kickbacks and, as a result, Biogen caused the submission of false or fraudulent claims to Medicare for Avonex or Tysabri associated with these payments.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorney's fees and costs.

Biogen denies that Relator is entitled to expenses, attorneys' fees, and costs.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Biogen shall pay to the United States twenty two million dollars (\$22,000,000) plus interest at a rate of 0.75% from November 3, 2020 through the day before full payment (the

“Settlement Amount”), no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the District of Massachusetts. Of the Settlement Amount, \$11,000,000 is restitution to the United States.

2. Conditioned upon the United States receiving the Settlement Amount from Biogen and as soon as feasible after receipt, the United States shall pay \$3,960,000 to Relator by electronic funds transfer.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Biogen’s full payment of the Settlement Amount, the United States releases Biogen, together with its predecessors, and its current and former, divisions, parents, subsidiaries, successors and assigns (the “Biogen Releasees”), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0, Subpart I, 0.45(d), or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 6 below, and conditioned upon Biogen’s full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the Biogen Releasees from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33.

5. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Biogen and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

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

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; and
- f. Any liability of individuals.

7. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil

Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases the Biogen Releasees, and their officers, agents, and employees, from any liability to Relator arising from the Covered Conduct or any other claims that were or should have been known to Relator at the time he filed the Civil Action, except that Relator, and his heirs, successors, attorneys, agents, and assigns shall retain all of his rights pursuant to the False Claims Act to recover from the Biogen Releasees his reasonable expenses, attorneys' fees, and costs pursuant to 31 U.S.C. § 3730(d), if any. No agreement concerning reasonable expenses, attorneys' fees, and costs has been reached to date. The Biogen Releasees retain and are not releasing their right to contest on any basis any Relator claim to an award of expenses, attorneys' fees, and costs.

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

10. Biogen fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Biogen has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Biogen fully and finally releases the Relator from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Biogen has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof. No agreement concerning Relator's reasonable expenses, attorneys' fees, and costs has been reached to date. Biogen retains and is not releasing its right to contest on any basis any Relator claim to an award of expenses, attorneys' fees, and costs.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Biogen agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

13. Biogen agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Biogen, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' investigation of the matters covered by this Agreement;

- (3) Biogen's investigation, defense, and corrective actions undertaken in response to the United States' and investigation in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Biogen makes to the United States pursuant to this Agreement and any payments that Biogen may make to Relator, including costs and attorneys fees

are unallowable costs for government contracting purposes and under the Medicare, Medicaid, TRICARE, and Federal Employees Health Benefits Programs.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Biogen, and Biogen shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Biogen or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, and Federal Employees Health Benefits Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Biogen further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and Federal Employee Health Benefit Program fiscal agents any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Biogen or any of its subsidiaries or affiliates,

and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Biogen agrees that the United States, at a minimum, shall be entitled to recoup from Biogen any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Biogen or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Biogen or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Biogen's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 3, 4, 7, 8, 10, 11 and 15.

15. Biogen agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action as follows

- a. dismissal shall be with prejudice as to the United States for the Covered Conduct;
- b. dismissal shall be without prejudice to the United States as to all other claims against Biogen in the Civil Action; and
- c. dismissal shall be with prejudice to Relator as to all claims against Biogen in the Civil Action.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement. This provision is not intended to affect any right of Relator to seek his expenses, attorneys' fees, and/or costs pursuant to 31 U.S.C. § 3730(d), and any right of Biogen to contest on any basis any such Relator claim for expenses, attorneys' fees, and/or costs.

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

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

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

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

23. This Agreement is binding on Biogen's successors, transferees, heirs, and assigns.

24. The Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

BY: [REDACTED]

ABRAHAM R. GEORGE
EVAN D. PANICH
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

BY: [REDACTED]

AUGUSTINE M. RIPA
SARAH ARNI

Attorney
Civil Division
United States Department of Justice

DATED: _____
BY: [REDACTED] 12/16/2020

LISA M. RE

Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

BIOGEN INC. - DEFENDANT

DATED: 12/11/20

BY:



MARTHA BORN
Chief Litigation Counsel
Biogen Inc.

DATED: 12/10/20

BY:



MICHAEL K. LOUCKS
Skadden, Arps, Slate, Meagher & Flom LLP
Counsel for Biogen

DATED: 12/10/2020

BY:




ALEXANDRA M. GORMAN
Skadden, Arps, Slate, Meagher & Flom LLP
Counsel for Biogen

PAUL NEE - RELATOR

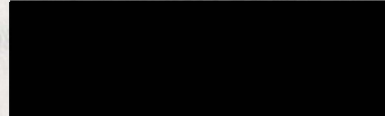
DATED: 12/10/20

BY:


PAUL NEE

DATED: _____

BY:


REUBEN GUTTMAN
TRACI BUSCHNER
JUSTIN BROOKS
ELIZABETH SHOFNER
Guttman, Buschner & Brooks, LLP
Counsel for Paul Nee

DATED: _____

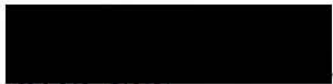
BY:

NANCY GERTNER
Fick & Marx LLP
Counsel for Paul Nee

PAUL NEE

DATED: 12/10/20

BY:



PAUL NEE

DATED: _____

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REUBEN GUTTMAN
TRACI BUSCHNER
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DATED: 12/14/20

BY:



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