#### 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"), Advanced Care Scripts, Inc. ("ACS"), and Paul Nee (the "Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

### **RECITALS**

- A. When a patient obtains a prescription drug, 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 beneficiaries of Federal healthcare programs to purchase, or their physicians to prescribe, the companies' drugs that are reimbursed by those programs.
- B. ACS is a Florida corporation with its principal office located in Orlando, Florida.

  ACS operates a specialty pharmacy and also has provided services to pharmaceutical companies.
- C. 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"). Relator alleges that Biogen, Inc. ("Biogen"), which manufactures multiple sclerosis ("MS") drugs, including Avonex and Tysabri, paid kickbacks to Medicare patients through third party foundations, and that, *inter alia*, ACS, as well as

CVS/Caremark, Omnicare, Inc., and Aetna Specialty Pharmacy LLC, (collectively, including ACS, the "ACS-Affiliated Entities") facilitated those kickbacks.

- D. The United States contends that ACS submitted, or caused the submission of, claims for payment for Avonex and Tysabri to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").
- E. The United States contends that it has certain civil claims, as specified below, against ACS for engaging in the conduct below during the period from January 1, 2008, through January 31, 2014 (hereinafter referred to as the "Covered Conduct"). Specifically, the United States alleges that ACS conspired with Biogen to enable Biogen to pay kickbacks to Medicare patients taking Avonex and Tysabri, as follows:
  - From approximately 2008 through January 2014, ACS served as a contracted vendor for Biogen.
  - 2. Pursuant to the agreement between Biogen and ACS, ACS received from Biogen information about certain Avonex patients whom ACS understood Biogen to have identified as being eligible for Medicare Part D prescription drug coverage. For identified Avonex patients who did not yet have Medicare Part D coverage, ACS assisted them in obtaining Medicare Part D coverage. Once Avonex patients had enrolled in a Medicare Part D plan, ACS assisted eligible patients in obtaining coverage for their Medicare Part D co-pays from third party foundations, including Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"). Biogen paid ACS a per-patient fee for its services. Once ACS had assisted an Avonex patient in obtaining co-pay coverage from a foundation, ACS often dispensed Avonex to that

- patient and submitted claims to Medicare Part D plans, or their agents, for the Avonex it dispensed.
- 3. Biogen sometimes provided ACS with advance notice of its intention to make a payment to CDF's or TAF's MS fund. In those instances, once ACS learned that CDF or TAF had re-opened its co-pay fund following such advance notice of a Biogen payment, ACS promptly would send the foundation a "batch file" that consisted almost entirely of Avonex patients' applications for Medicare co-pay coverage. Thereafter, ACS often received notice from the foundation that most or all of the applications submitted by ACS for Biogen patients had been approved to receive co-pay funding. At certain times, ACS shared with Biogen lists of Avonex patients for whom ACS had helped to obtain co-pay coverage from a foundation. At least one ACS employee understood that Biogen used that information to correlate its payments to CDF and TAF with the amounts of money the foundations needed to cover Medicare co-pays for Avonex patients.
- 4. In 2012 and 2013, at Biogen's direction, ACS also assisted Tysabri patients in obtaining coverage for their Medicare Part B co-pays from TAF and/or CDF. ACS understood that patients seeking co-pay funding for Medicare Part D drugs typically applied for and received grants for such funding in the first quarter of each calendar year, and that patients seeking co-pay funding for Medicare Part B drugs, such as Tysabri, typically applied for and received co-pay grants for such funding throughout the calendar year. In 2012 and 2013, Tysabri was the only MS drug for which the Medicare Part B program provided reimbursement. On certain occasions in 2012 and 2013 when Biogen provided ACS advance notice of its intention to make a payment

to TAF or CDF and ACS learned that TAF or CDF re-opened its co-pay fund following such advance notice of a payment from Biogen, ACS transmitted co-pay funding applications to CDF or TAF for Tysabri patients identified by Biogen, and those patients received co-pay funding from TAF or CDF.

As a result of the foregoing conduct, the United States contends that ACS caused false claims to be submitted to Medicare.

ACS acknowledges the facts set forth in paragraphs E.1-E.4 above.

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

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

#### TERMS AND CONDITIONS

- 1. ACS shall pay to the United States one million four hundred thousand dollars (\$1,400,000) (the "Settlement Amount") no later than ten days after the Effective Date of this Agreement (defined in Paragraph 26, below), by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts. Of the Settlement Amount, \$700,000 constitutes restitution to the United States.
- 2. Conditioned upon the United States receiving the Settlement Amount from ACS and as soon as feasible after receipt, the United States shall pay \$224,000 to Relator by electronic funds transfer. Separately, ACS agrees to pay Relator's attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in a separate agreement being entered into simultaneously with the execution of this Agreement.

- 3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon ACS's full payment of the Settlement Amount, the United States releases ACS (including its predecessors, and current and former divisions, parents, subsidiaries, successors and assigns) from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, 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 ACS's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the ACS-Affiliated Entities (including their predecessors, and current and former divisions, parents, subsidiaries, successors and assigns) from any civil monetary claim Relator has on behalf of the United States for the conduct alleged in the Civil Action and for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.
- 5. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against ACS 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 release given in paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:
  - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
  - b. Any criminal liability;

- 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. ACS waives and shall not assert any defenses ACS 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.
- 9. ACS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that ACS 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.

- 10. ACS fully and finally releases Relator from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that ACS has asserted, could have asserted, or may assert in the future against Relator, related to the Covered Conduct and Relator's investigation and prosecution thereof.
- 11. 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 ACS 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.

### 12. ACS agrees to the following:

- a. <u>Unallowable Costs Defined</u>: 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 ACS, its present or former officers, directors, employees, shareholders, and agents in connection with:
  - (1) the matters covered by this Agreement;
  - the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
  - (3) ACS's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal

- investigation(s) 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 ACS makes to the United States pursuant to this Agreement and any payments that ACS may make to Relator, including costs and attorney's fees

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by ACS, and ACS 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 ACS or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: ACS 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 FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by ACS 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. ACS agrees that the United States, at a minimum, shall be entitled to recoup from ACS 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 ACS or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on ACS 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 ACS's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 13. ACS agrees to cooperate fully and truthfully with the United States' investigation of the Covered Conduct as to unaffiliated individuals and entities not released in this Agreement. Upon reasonable notice, ACS agrees not to impair the cooperation of its directors, officers, and employees, and shall use its best efforts to make available the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. ACS further agrees to furnish to the United States, upon reasonable request, complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

- 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 this Agreement, including Paragraph 15 (waiver for beneficiaries paragraph), below.
- 15. ACS 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 to ACS and/or the ACS-Affiliated Entities, including ACS's and the ACS-Affiliated Entities' predecessors, and current and former divisions, parents, subsidiaries, successors and assigns, as follows:
  - a. dismissal shall be with prejudice as to the United States' claims against
     ACS as to the Covered Conduct;
  - b. dismissal shall be without prejudice to the United States as to all other claims against ACS and/or the ACS-Affiliated Entities in the Civil Action; and
  - dismissal shall be with prejudice to Relator as to all claims against ACS
     and the ACS-Affiliated Entities 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.
- 18. Each party and signatory to this Agreement represents that it freely and voluntarily enters into 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 ACS's successors, transferees, heirs, and assigns.
  - 24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.
- 25. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 26. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

## THE UNITED STATES OF AMERICA

DATED:		BY:		
			ABRAHAM R. GEORGE EVAN PANICH GREGG SHAPIRO Assistant United States Attorneys United States Attorney's Office District of Massachusetts	
	1,600			

DATED: <u>B/16/26</u> BY:

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

# ADVANCED CARE SCRIPTS, INC.

**DATED:** 12/11/20 **BY** 

I HUMAS S. MUTTAI I

President

Advanced Care Scripts, Inc.

**DATED:** 12/11/20

11/20 **BY**:

S. CRAIG HULDEN

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC Counsel for Advanced Care Scripts, Inc.

## PAUL NEE

DATED: <u>/a//0/a0</u>	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: 13/10/20	BY:	PAUL NEE
DATED:	BY:	REUBEN GUTTMAN TRACI BUSCHNER JUSTIN BROOKS ELIZABETH SHOFNER Guttman, Buschner & Brooks, LLP Counsel for Paul Nee
DATED: (2/14/20	BY:	Fick & Marx LLP Counsel for Paul Nee