SETTLEMENT AGREEMENT

This Settlement Agreement ("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"), and The Assistance Fund, Inc. ("TAF") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. 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 that are reimbursed by Medicare.

B. TAF is a Delaware corporation with its principal office located in Orlando, Florida. TAF operates funds that receive payments from pharmaceutical manufacturers and others, and that then use those payments, less administrative fees that TAF charges, to cover the drug co-pay obligations of patients, including Medicare patients.

C. The United States contends that TAF received payments from pharmaceutical manufacturers Teva Pharmaceuticals USA, Inc. ("Teva"), which sells Copaxone, Biogen Inc. ("Biogen"), which sells Tysabri and Avonex, and Novartis Pharmaceuticals Corporation ("Novartis"), which sells Gilenya, and then caused to be submitted claims for payment for Copaxone, Tysabri, and Gilenya to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

D. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against TAF for engaging in the conduct below (hereinafter referred to as the "Covered Conduct"). Specifically, the United States alleges that TAF, under the direction and/or control of its former management, conspired with Teva, Biogen, and Novartis to enable them to pay kickbacks to Medicare patients taking certain of their drugs, as follows:

TAF's solicitation and receipt of payments from Teva that correlated with TAF's spending on Copaxone renewal patients. In the month of December prior to each of the years 2011-2015, TAF conveyed to Teva how much money TAF's multiple sclerosis ("MS") fund needed to renew co-pay grants for the fund's existing Copaxone patients in the upcoming year. In order to determine these amounts, which ranged from over $18 million to over $30 million, TAF multiplied the number of Copaxone patients in the fund by the fund's average grant amount, and then added the cost of TAF's administrative fee. TAF understood that Teva knew how TAF was calculating the amounts of these funding requests, and that, accordingly, Teva was using TAF's MS fund as a conduit to cover Medicare co-pays for Copaxone patients.

TAF's practice of not maintaining wait lists and its coordination of the openings of the MS fund with Teva, Biogen, and Novartis. During the period from 2011-2014, TAF's MS fund frequently ran out of funding and was closed to new patients. If any patients applied for co-pay assistance at a time when the MS fund was out of funding and closed to new patients, TAF did not maintain a wait list of such patients. As a consequence, whenever TAF's MS fund received a payment and opened to new patients, the fund provided grants to the patients who applied immediately after the opening and did not provide grants to patients who had sought to apply earlier but at a time when the fund was closed. As described further below, TAF's practice of not maintaining wait lists enabled TAF to coordinate with certain pharmaceutical manufacturers

to ensure that TAF used their funding to cover the co-pays of patients taking the manufacturers' drugs.

During the period from 2011 to 2014, Teva not only made large payments to TAF's MS fund in January of each year, Teva also made numerous smaller payments, typically less than $3 million each, to TAF's MS fund at subsequent times during each year. In conjunction with each of these smaller payments, TAF coordinated with Teva and Teva's vendor, Advanced Care Scripts ("ACS"), to ensure that Copaxone patients received a disproportionate share of the grants from the fund during each window when the fund opened after a Teva payment. Each time that Teva was prepared to make a payment, TAF understood that ACS had told Teva how many Copaxone patients were awaiting assistance. Meanwhile, TAF had told Teva the average MS fund grant amount at the time of the payment. TAF knew that Teva was multiplying the average grant amount by the number of waiting Copaxone patients to determine the amounts of its payments to TAF's fund. TAF further knew that, whenever Teva made a payment to TAF's MS fund and the fund opened, ACS immediately would send a "batch file" of Medicare co-pay assistance applications for Copaxone patients. As a result, each time TAF's MS fund opened after one of Teva's post-January payments during this period, Copaxone patients received a substantial majority of the grants that the fund provided, even though Copaxone accounted for much less than a majority of the overall MS drug market. Further, TAF maintained a "portal" that gave ACS real-time access to the enrollment status of the patients ACS referred; the portal, as TAF knew, enabled ACS to update Teva on the number of Copaxone patients who had received grants from TAF's MS fund.

Biogen made payments to TAF's MS fund on May 24 and July 17, 2012, as part of a coordinated effort – which, in an e-mail to a Biogen vice president, TAF's co-founder termed the

"TYS[abri] project" – by TAF and Biogen to use Biogen's money to cover Medicare co-pays for Tysabri patients. TAF knew that, when the fund opened after each of these two Biogen payments, ACS immediately would send a "batch file" of Medicare co-pay assistance applications for Tysabri patients. As a result, when TAF's MS fund opened after Biogen's payments on May 24 and July 17, 2012, Tysabri patients received a disproportionate share of the grants that the fund provided. Subsequently, TAF reported to Biogen, both directly and through ACS, TAF's success in directing Biogen's funding to Tysabri patients.

Beginning in October 2012, TAF and Novartis began to coordinate on a means of ensuring that Novartis's next payment to TAF's MS fund would go almost exclusively to Gilenya patients. Ultimately, TAF and Novartis agreed that Novartis would pay TAF's MS fund $1,418,000 and TAF would open the fund at 6:00 p.m. on Friday, December 14, 2012. At the time, TAF knew that Novartis had arranged for staff from Novartis's vendor, Express Scripts, to work overtime that night and the following morning to refer Gilenya patients to TAF's MS fund for Medicare co-pay assistance. Express Scripts and TAF referred to this effort as their "12/15 Saturday project." TAF knew that the timing of the opening of the fund and the readiness of Express Scripts to submit applications on behalf of Gilenya patients at that time would result in Gilenya patients receiving a disproportionate share of the grants from the fund while it was open. After the fund closed on Saturday, December 15, 2012, TAF confirmed that, during the brief period the fund had been open, TAF used Novartis's money to provide 374 Gilenya patients and 6 non-Gilenya patients with grants for Medicare co-pay assistance in 2013.

TAF's discrimination against Tysabri patients in 2014. In late December 2012, Biogen provided TAF's MS fund with funding that TAF understood was to cover grant renewals in 2013 for patients on Biogen's MS drugs – Tysabri and Avonex. During 2013, TAF applied that

Biogen funding to grants that included patients on Biogen's drugs. In late 2013, TAF learned that Biogen did not intend to support TAF's MS fund for 2014. At the time, TAF also knew that the Medicare co-pay for Tysabri was significantly higher than the Medicare co-pays for the other MS drugs TAF's MS fund covered. Because Biogen would not support TAF's MS fund in 2014, and because the co-pays for Tysabri were higher than for other MS drugs, TAF decided not to renew co-pay assistance grants to a number of Tysabri patients in 2014, thereby increasing the available funding for assistance to patients taking drugs made by companies such as Teva that were continuing to finance TAF's MS fund.

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

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

TERMS AND CONDITIONS

1. TAF shall pay to the United States four million dollars ($4,000,000) (the "Settlement Amount") no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for District of Massachusetts.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon TAF's full payment of the Settlement Amount, the United States releases TAF, together with its predecessors, and its 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. §§ 3729-33, 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.

3. In consideration of the obligations of TAF in this Agreement and the Integrity Agreement ("IA") entered into between OIG-HHS and TAF, and conditioned upon TAF's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against TAF under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude TAF from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in paragraphs 2 and 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;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory 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;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. TAF has provided sworn financial disclosure statements ("Financial Statements") to the United States, and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. TAF warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which TAF had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by TAF on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by $250,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of TAF previously undisclosed. TAF agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

6. In the event that the United States, pursuant to Paragraph 5 (concerning disclosure of assets), above, opts to rescind this Agreement, TAF agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to TAF that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on April 1, 2019.

7. TAF waives and shall not assert any defenses TAF 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.

8. TAF 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 TAF has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. 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 TAF 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.

10. TAF 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of TAF, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s), and any civil or criminal investigations of the matters covered by this Agreement;

(3) TAF's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and any civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment TAF makes to the United States pursuant to this Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the IA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the IA; and (ii) prepare and submit reports to the OIG-HHS,

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"). However, nothing in paragraph

10.a.(6) that may apply to the obligations undertaken pursuant to the IA affects the status of costs that are not allowable based on any other authority applicable to TAF.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by TAF, and TAF 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 TAF or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: TAF 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 TAF 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. TAF agrees that the United States, at a minimum, shall be entitled to recoup from TAF 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 TAF or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on TAF 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 TAF's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

11. TAF agrees to cooperate fully and truthfully with the United States' investigation of the Covered Conduct, or any litigation as to claims related to it, as to unaffiliated individuals and entities not released in this Agreement. Upon reasonable notice, TAF shall encourage, and agrees not to impair, the cooperation of its directors, officers and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. TAF further agrees to voluntarily 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 that could be obtained by subpoena in any enforcement matter concerning the Covered Conduct and such materials including non-privilege reports and memoranda of interviews concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

12. 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 Paragraph 13 (waiver for beneficiaries paragraph), below.

13. TAF 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.

14. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. 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.

16. 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.

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

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

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

20. This Agreement is binding on TAF's successors, transferees, heirs, and assigns.

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

22. 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

DATED: 11/20/2019 **BY:** _____

GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 11/20/2019 **BY:** _____

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

THE ASSISTANCE FUND, INC.

DATED: 11/19/2019 **BY:** _____
MARK McGREEVY
President
The Assistance Fund, Inc.

DATED: 11/19/19 **BY:** _____
MICHAEL CONNOLLY
LAURA ANGELINI
Hinckley Allen
Counsel for The Assistance Fund, Inc.