

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 Chronic Disease Fund, Inc., d/b/a Good Days from CDF (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 “copays”). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

B. Chronic Disease Fund, Inc., d/b/a Good Days from CDF (“CDF”), is a Texas non-profit corporation with its principal office located in Plano, Texas. CDF operates funds that receive payments from pharmaceutical manufacturers and others, and that then use those payments, less administrative fees that CDF charges, to cover the drug copay obligations of patients, including Medicare patients.

C. The United States contends that CDF received payments from pharmaceutical manufacturers Dendreon Corp. (“Dendreon”), which sells Provenge, Astellas Pharma US, Inc. (“Astellas”), which sells Xtandi, Novartis Pharmaceuticals Corporation (“Novartis”), which sells Afinitor, Onyx Pharmaceuticals, Inc. (“Onyx”) (now owned by Amgen Inc.), which sells Kyprolis, and Questcor Pharmaceuticals, Inc. (“Questcor,” now Mallinckrodt ARD Inc.), which sells H.P. Acthar Gel (“Acthar”), and then caused to be submitted claims for payment for

Provenge, Xtandi, Afinitor, Kyprolis, and Acthar 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 CDF for engaging in the conduct below (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges that, between January 1, 2010, and December 31, 2014, CDF conspired with Dendreon, Astellas, Novartis, Onyx, and Questcor to enable them to pay kickbacks to Medicare patients taking their drugs, as follows:

CDF’s Provision of Data to Dendreon for the mCRPC Fund. Provenge is an immunotherapy which the FDA approved in April 2010 for treatment of metastatic castrate-resistant prostate cancer (“mCRPC”). In or about January 2010, Dendreon contacted CDF to request that CDF create a mCRPC fund. At that time, Provenge’s principal competitor therapy was Taxotere, a less costly injectable therapy indicated for treatment of various types of cancer. CDF opened its mCRPC fund in June 2010, and, from that time until August 2011, Dendreon was the sole source of funding for CDF’s mCRPC fund. From June 2010 through 2011, at Dendreon’s request and on multiple occasions, CDF provided Dendreon with data concerning the number of Provenge patients receiving assistance from CDF’s mCRPC fund, the number of Taxotere patients receiving assistance from CDF’s mCRPC fund, and the average amount of financial assistance CDF’s mCRPC fund was providing to Provenge and Taxotere patients, respectively. In May 2011, following the FDA approval of Zytiga, an oral therapy indicated for treatment of mCRPC, CDF also provided Dendreon with information concerning the number of Zytiga patients receiving assistance from CDF’s mCRPC fund. CDF’s provision of this information to Dendreon made it possible for Dendreon to correlate its payments to CDF’s mCRPC fund with the fund’s spend on financial assistance for patients taking Provenge.

CDF's ARI Copay Fund. Xtandi is indicated for treatment of mCRPC for patients who have failed chemotherapy. After the launch of Xtandi in September 2012, Astellas provided funding for the mCRPC fund at CDF. Xtandi is an androgen receptor inhibitor (“ARI”); none of the other major mCRPC drugs, including Xtandi’s main competitor, is an ARI. In May 2013, Astellas contacted CDF to request the opening of an ARI fund, which would cover mCRPC patients’ copays for ARIs, but not for other mCRPC drugs. CDF knew this meant that Astellas was seeking to earmark money for Xtandi patients, and not others, because Xtandi was the dominant ARI drug for treatment of mCRPC. On July 1, 2013, at Astellas’ request, CDF opened an ARI fund. Astellas was the only funder of CDF’s ARI fund. As CDF intended, Xtandi patients received nearly all of the assistance from CDF’s ARI fund. CDF closed its ARI fund at the end of 2013.

CDF's PNET Copay Fund. In May 2011, Afinitor was approved to treat progressive neuroendocrine tumors of pancreatic origin (“PNET”). In 2012, Novartis asked CDF to open a copay assistance fund to cover Afinitor copays for PNET patients. At that time, CDF knew that another drug, made by a different manufacturer, also was approved to treat PNET. In August 2012, at Novartis’ request, CDF opened a supposed “PNET” fund to pay Afinitor copays. The fund, which was funded solely by Novartis, covered copays only for Afinitor; it did not cover copays for the other drug approved to treat PNET.

CDF's Multiple Myeloma Travel Fund. In July 2012, Onyx received approval to market Kyprolis as a third-line treatment for multiple myeloma. Kyprolis must be infused at a health care facility. At around the time of the approval, Onyx asked CDF to create a fund that, ostensibly, would cover health care related travel expenses for patients taking any multiple myeloma drug. At Onyx’s request, CDF created the fund, which was funded solely by Onyx.

Internally, CDF at times referred to the fund as the “Kyprolis Travel” fund, and, in fact, it functioned primarily to cover travel expenses for patients taking Kyprolis, including Medicare patients.

CDF’s Provision of Data to Onyx for the Multiple Myeloma Copay Fund. CDF operated a fund that covered copays for multiple myeloma drugs, including Kyprolis and several other drugs. CDF’s multiple myeloma copay fund received payments from several pharmaceutical manufacturers. In 2013, CDF provided Onyx with data detailing the amount CDF had spent, and anticipated spending, on Kyprolis copays. This enabled Onyx to view CDF’s funding requests as seeking amounts necessary to pay Kyprolis copays but not the copays of any other multiple myeloma drug. In 2013, after receiving this information, Onyx paid CDF just enough to cover CDF’s anticipated spending on copays for Kyprolis patients.

CDF’s MS, Lupus, and RA “Exacerbation” Funds. In 2010, 2011, and 2012, respectively, Questcor approached CDF and requested that CDF open a multiple sclerosis (“MS”) “exacerbation” fund, a Lupus “exacerbation” fund, and a Rheumatoid Arthritis (“RA”) “exacerbation” fund, that would each pay the Medicare copays for patients taking Acthar but not any other MS, Lupus, or RA drug. In each case, after Questcor’s request, CDF opened these “exacerbation” funds, which paid Acthar copays exclusively, sometimes for patients taking Acthar continuously for months or years. Questcor was the sole donor to each fund and CDF received the vast majority of its patient referrals to each fund from Questcor. After establishing the funds, CDF provided financial reports to Questcor that enabled Questcor to determine how much of its donations had already been spent on Acthar patients and how much more money would be necessary to pay the Acthar copays for patients Questcor referred to CDF.

As a result of the foregoing conduct, the United States contends that CDF 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. CDF shall pay to the United States two million dollars (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 CDF’s full payment of the Settlement Amount, the United States releases CDF, 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 CDF in this Agreement and the Integrity Agreement (“IA”) entered into between OIG-HHS and CDF, and conditioned upon CDF’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 CDF 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 CDF 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. CDF 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. CDF warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which CDF 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 CDF 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 CDF previously undisclosed. CDF 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, CDF 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 CDF that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on January 18, 2018.

7. CDF waives and shall not assert any defenses CDF 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. CDF 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 CDF 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 CDF 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. CDF 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 CDF, 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) CDF'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 CDF 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 CDF.

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

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

11. CDF 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, CDF 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. CDF further agrees voluntarily 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 that could be obtained by subpoena in any enforcement matter concerning the Covered Conduct and such materials including non-privileged 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. CDF 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.

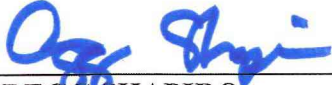
19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.


20. This Agreement is binding on CDF'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.

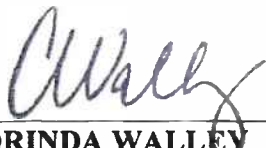
THE UNITED STATES OF AMERICA

DATED: 10/24/19 BY: 
GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 10/23/2019 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

CHRONIC DISEASE FUND, INC.

DATED: 10/24/19

BY: 
CLORINDA WALLEY
President
Chronic Disease Fund, Inc.

DATED: 10/21/19

BY: LISA KEENAN / *W PERMISSION CJT*
ROBERT ZINKHAM
LISA KEENAN
Miles & Stockbridge PC
Counsel for Chronic Disease Fund, Inc.

DATED: 10/24/19

BY: JOSEPH SAVAGE / *W PERMISSION CJT*
JOSEPH SAVAGE
Goodwin Procter LLP
Counsel for Chronic Disease Fund, Inc.