

## 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 Patient Access Network Foundation (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. Patient Access Network Foundation (“PANF”), is a District of Columbia non-profit corporation with principal executive offices located in Washington, D.C. PANF operates disease funds that receive funding from pharmaceutical manufacturers and then uses the funds, less administrative fees that PANF charges, to cover the drug copay obligations of patients, including Medicare patients.

C. The United States contends that, between 2011 and 2014, PANF received payments from pharmaceutical manufacturers Astellas Pharma US, Inc. (“Astellas”), which sells Xtandi, Bayer Pharmaceuticals, Inc. (“Bayer”), which sells Xofigo, Dendreon Pharmaceuticals LLC (“Dendreon”), which sells Provenge, and Amgen Inc. (“Amgen”), which sells Sensipar, and then caused claims for payment for Xtandi, Xofigo, Provenge, and Sensipar to be submitted 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 PANF for engaging in the conduct below during the period from 2011 through 2014 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges that PANF permitted Astellas, Bayer, Dendreon, and Amgen to use PANF as a conduit to pay kickbacks, in the form of reimbursement for out of pocket expenses, to Medicare patients taking certain of their drugs, as follows:

The Prostate Cancer Subfunds. In March 2010, PANF opened a fund that covered copays for patients taking any drug that treated prostate cancer. In September 2012, PANF opened a fund that covered copays for patients taking drugs that treated metastatic castrate-resistant prostate cancer (“mCRPC”), a type of prostate cancer. PANF’s mCRPC fund covered a number of drugs, including Zytiga, Xtandi, Xofigo, and Provenge. In the months after PANF opened its mCRPC fund, the fund spent more on copay claims for Zytiga than for any other drug.

Xofigo is an alpha particle-emitting radioactive therapeutic agent that the Food and Drug Administration (“FDA”) approved to treat mCRPC on May 15, 2013. None of the other major drugs to treat mCRPC, including Zytiga, Xtandi, and Provenge, is radioactive. Prior to the approval of Xofigo, Bayer approached PANF about creating a fund that would cover only radioactive drugs for mCRPC. On May 16, 2013, one day after the FDA approved Xofigo, PANF opened a fund called Radioisotope Treatment of Metastatic Castrate Resistant Prostate Cancer (“RIT”). Bayer was the sole donor to PANF’s RIT fund. Until PANF merged the fund into the mCRPC fund in February 2014, Xofigo patients received nearly all of the assistance from PANF’s RIT fund.

Xtandi is an androgen receptor inhibitor (“ARI”) drug that the FDA approved to treat mCRPC in 2012. None of the other major drugs to treat mCRPC, including Zytiga, Xofigo, and Provenge, is an ARI. After hearing about PANF’s RIT fund, Astellas contacted PANF about creating an ARI fund that would cover only ARI drugs for mCRPC. On July 1, 2013, PANF opened an ARI fund. PANF merged the ARI fund into the mCRPC fund in February 2014, but for the remainder of 2014 PANF continued to pay the copays for patients who had received grants from the ARI fund prior to the merger. Astellas was the sole donor to PANF’s ARI fund. Xtandi patients received the great majority of the assistance from PANF’s ARI fund.

Provenge is an immunotherapy treatment for mCRPC. None of the other major drugs to treat mCRPC, including Zytiga, Xofigo, and Xtandi, is an immunotherapy. Approximately one month after the opening of PANF’s RIT fund, PANF and Dendreon began discussions about PANF creating a fund that would cover copays only for immunotherapy treatments for mCRPC. On August 2, 2013, PANF opened a fund called Immunotherapy for Genitourinary Cancer (“GU”). Dendreon was the sole donor to PANF’s GU fund. Until PANF merged the fund into the mCRPC fund in mid-2014, Provenge patients received nearly all of the assistance from PANF’s GU fund.

The SHPT Fund. Sensipar is approved by the FDA to treat secondary hyperparathyroidism (“SHPT”) in adult patients with chronic kidney disease on dialysis. The FDA also has approved other drugs to treat SHPT. In September 2011, Amgen approached PANF about creating an SHPT fund. PANF and Amgen then worked together to determine the fund’s coverage parameters so that it would cover only Sensipar. In November 2011, PANF launched a SHPT fund with Amgen as its sole donor. Until June 2014, Sensipar patients received all of the assistance from PANF’s SHPT fund.

As a result of the foregoing conduct, the United States contends that PANF 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. PANF shall pay to the United States four 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 PANF’s full payment of the Settlement Amount, the United States releases PANF, 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 PANF in this Agreement and the Integrity Agreement (“IA”) entered into between OIG-HHS and PANF, and conditioned upon PANF’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 PANF 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 PANF 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. PANF has provided sworn financial disclosure statements and follow up information (“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. PANF warrants that the Financial Statements are complete, accurate, and current as of the date submitted. If the United States learns of asset(s) in which PANF had an interest at the time of this Agreement that were not disclosed in the Financial Statements, other than donations subsequently received or investment income earned in the ordinary course of PANF’s operations or if the United States learns of any misrepresentation by PANF 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 PANF previously undisclosed. PANF 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, PANF 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 PANF that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on March 2, 2018.

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

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

c. Treatment of Unallowable Costs Previously Submitted for Payment:

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

11. PANF 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, PANF 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. PANF 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. PANF 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 PANF'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.

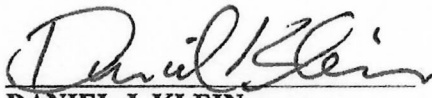
22. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

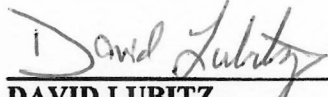
THE UNITED STATES OF AMERICA

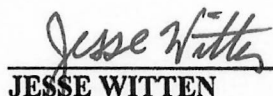
DATED: 10/24/19 BY:   
GREGG SHAPIRO  
ABRAHAM GEORGE  
Assistant United States Attorneys  
United States Attorney's Office  
District of Massachusetts

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

PATIENT ACCESS NETWORK FOUNDATION

DATED: 10/24/2019 BY:   
**DANIEL J. KLEIN**  
President and Chief Executive Officer  
Patient Access Network Foundation

DATED: 10/24/19 BY:   
**DAVID LUBITZ**  
Schaner and Lubitz, PLLC  
Counsel for Patient Access Network Foundation

DATED: 10/24/19 BY:   
**JESSE WITTEN**  
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