UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et. al*, *ex rel.* KREGG EVERETT, Plaintiffs, v. GENPATH DIAGNOSTICS, BIO-REFERENCE LABORATORIES, INC., and CYTOMETRY SPECIALISTS, INC., Defendants.	**10 Civ. 4212 (GBD)**
UNITED STATES OF AMERICA *ex rel.* SAMUEL RUTA and BLAIR CONROY, Plaintiffs, v. BIO-REFERENCE LABORATORIES, INC., Defendant.	**11 Civ. 3850 (GBD)**
UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. BIO-REFERENCE LABORATORIES, INC., Defendant.	

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal ("Stipulation") is entered into by and among plaintiff the United States of America (the "United States" or "Government"), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York; the relator Kregg Everett ("Everett"); the relators Samuel Ruta and Blair Conroy ("Ruta and Conroy," and together with Everett, the "Relators"); and Defendant Bio-Reference Laboratories, Inc. ("BRL" or "Defendant," and together with the Government and the Relators, the "Parties"), through their authorized representatives;

WHEREAS, BRL provides laboratory testing to healthcare providers focusing on molecular diagnostics, anatomical pathology, genetics, and women's health;

WHEREAS, in August 2015, a subsidiary of OPKO Health Inc. ("OPKO") merged with and into BRL, with BRL surviving the merger as a wholly owned subsidiary of OPKO and continuing to provide laboratory testing;

WHEREAS, on or about May 25, 2010, Everett filed a complaint under the *qui tam* provisions of the civil False Claims Act ("FCA"), as amended, 31 U.S.C. § 3729 *et seq.*, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) ("AKS"), which alleges, *inter alia*, that BRL and its division Genpath Diagnostics, in violation of the FCA and AKS, fraudulently billed Medicare for certain testing performed for hospital inpatients that the hospitals were required to pay themselves, in order to induce hospitals to order more testing from BRL (the "Everett Complaint");

WHEREAS, on or about December 16, 2010, Ruta and Conroy filed a complaint in the United States District Court for the District of New Jersey under the *qui tam* provisions of the FCA, which alleges, *inter alia*, that BRL, in violation of the FCA and AKS: (i) fraudulently billed Medicare for certain testing performed for hospital inpatients that the hospitals were required to

pay for themselves, and (ii) engaged in a fraudulent kickback scheme by providing a percentage of the cost of medical records transition software to physicians' offices based on the volume of business generated by those offices (the "Ruta-Conroy Complaint");

WHEREAS, on April 16, 2011, the Ruta-Conroy Complaint was transferred to this District;

WHEREAS, the Centers for Medicare and Medicaid Services ("CMS") require independent laboratories, like BRL, to bill hospitals for laboratory tests that are (a) listed on the Clinical Lab Fee Schedule ("CLFS"), 42 C.F.R. § 414 *et seq*., and (b) furnished to Medicare and Tricare inpatients, because hospitals receive payments for all items and services provided to the patient under the inpatient prospective payment system ("IPPS"), unless an exemption applies. Specifically, 42 C.F.R. §§ 411.15(m)(1) & (2) exclude from Medicare and Tricare coverage a list of clinical laboratory services, provided to hospital inpatients, and the laboratory services subject to the exclusion varied by year;

WHEREAS, the AKS prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, . . . in cash or in kind to any person to induce such person" to obtain "any item or service for which payment may be made in whole or in part under a federal health care program," 42 U.S.C. § 1320a-7b(b)(2);

WHEREAS, in August 2006, the Office of the Inspector General for the Department of Health and Human Services promulgated final rules permitting any Medicare supplier or provider, including an independent laboratory, to donate to any "individual or entity engaged in the delivery of health care," including a physician, a percentage of the costs of electronic medical records software or information technology and training services (the "EMR Safe Harbor"). A donation qualifies for the EMR Safe Harbor only if "[n]either the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly

takes into account the volume or value of referrals or other business generated between the parties," 12 C.F.R. § 1001.952(y)(5);

WHEREAS, the Government alleges that: (1) during the period 2009 through 2012, BRL fraudulently billed Medicare and Tricare for certain testing performed for hospital inpatients and listed on the CLFS, which should have been paid by the hospitals themselves ("Inpatient Testing Covered Conduct"), and (2) during the period 2009 through 2012, BRL knowingly offered and paid remuneration, in the form of a percentage of the cost of electronic medical records transition software, to physicians based on the volume of business generated by those physicians in order to induce them to use BRL's services ("EMR Software Donation Covered Conduct"). This Inpatient Testing Covered Conduct and the EMR Software Donation Covered Conduct are referred to collectively as the "Covered Conduct";

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Partially Intervene and Complaint-In-Intervention in the above-referenced *qui tam* actions ("Government Complaint"), in which it is asserting claims against BRL under the FCA for the Covered Conduct;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against BRL in the Government Complaint for the Covered Conduct, and the claims asserted against BRL in the Everett Complaint and the Ruta-Conroy Complaint;

WHEREAS, the Relators' claims to a share of the proceeds from the settlement between the Parties will be the subject of a separate agreement between the Relators and the United States;

NOW, THEREFORE, upon the Parties' agreement, IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.

2. Defendant admits, acknowledges, and accepts responsibility for the following conduct:

a. From 2009 through 2012, BRL billed Medicare and Tricare for certain testing (i) listed on the CLFS and (ii) performed on beneficiaries who were hospital inpatients at the time of service.

b. Specifically, from 2009-2012, approximately 2.51% of all of BRL's Medicare and Tricare billing originating from hospitals consisted of testing performed on hospital inpatients and listed on the CLFS.

c. For example, from 2009-2012, BRL did not bill Triad of Alabama/Flowers Hospital in Dothan, Alabama ("Triad"), for any inpatient testing. As a result, from 2009-2012, BRL improperly billed Medicare and Tricare for approximately 2.51% of all testing BRL performed for Triad and its associated pathology practices on behalf of Medicare or Tricare beneficiaries.

d. In 2009, BRL's requisition form – the form BRL provided to hospitals to order tests for their patients – did not contain any place for a hospital to indicate whether the patient was an inpatient or an outpatient. But as of at least January 2010, BRL management had a clear understanding of the necessity to bill hospitals – and not Medicare or Tricare – for testing performed on hospital inpatients and listed on the CLFS. Indeed, on January 27, 2010, the Director of Genpath Accounts Receivable wrote to management, "I'm afraid that we can end up billing Medicare for hospital patients." Nevertheless, the requisition forms remained the same, and through at least 2012, BRL billed Medicare and Tricare for hospital inpatient testing listed on the CLFS.

e. In addition, from 2009 through 2012, BRL provided a percentage of the cost of electronic medical records transition software ("EMR Software") to physicians' offices based on the volume of business generated by those offices.

f. Specifically, from 2009 through 2012, BRL engaged in a practice – at the direction of its management – entitled the "3 to 1 calculation," meaning that BRL conditioned the provision of payment for EMR Software to physicians' offices on whether a physician's office would generate revenue equal to three times the value of the EMR Software BRL provided.

g. For example, on January 24, 2009, a BRL employee, in an email to BRL management, applied the 3 to 1 calculation to a particular physician's office and suggested that BRL provide the payment for EMR Software, but noted, "You find the legal way to say that. I don't feel they will make us put it in writing."

h. Similarly, on January 7, 2011, BRL management evaluated a BRL salesperson's request for payment for EMR Software to a particular physician's office, and directed that salesperson to "[b]uild volume to meet 3x rule."

i. During this timeframe, BRL provided payment for EMR Software based on this formula to sixty-nine separate physicians' offices.

3. Defendant shall pay to the Government the sum of **$11,500,960.00 plus interest** which shall be compounded annually at a rate of 1.25% accruing from March 2, 2020 ("Settlement Amount") in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, **$5,750,480.00** constitutes restitution to the United States. The sum of $1,396,386.00 (plus interest) is being paid to resolve claims for the Inpatient Testing Covered Conduct, and the sum of $10,104,574.00 (plus interest) is being paid to resolve claims for the EMR Software Donation Covered Conduct. The Settlement Amount shall be paid pursuant to the following schedule:

a. Within fourteen (14) business days of the Effective Date (defined below in Paragraph 32), Defendant shall pay the United States the sum of $2,875,240, plus interest which shall be compounded annually at a rate of 1.25% accruing from March 2, 2020.

b. On or before ninety-four (94) business days from the Effective Date, Defendant shall pay the United States the sum of $2,875,240, plus interest

which shall be compounded annually at a rate of 1.25% accruing from March 2, 2020.

c. On or before one hundred seventy-four (174) business days from the Effective Date, Defendant shall pay the United States the sum of $2,875,240, plus interest which shall be compounded annually at a rate of 1.25% accruing from March 2, 2020.

d. On or before one year from the Effective Date, Defendant shall pay the United States the sum of $2,875,240, plus interest which shall be compounded annually at a rate of 1.25% accruing from March 2, 2020.

OPKO will serve as guarantor of BRL's obligation to pay the Settlement Amount, as outlined Exhibit B.

4. Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, BRL shall encourage, and agree not to impair, the cooperation of its and OPKO's directors, officers, and employees, and shall use their 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. BRL further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, 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.

5. Subject to the exceptions in Paragraphs 12 and 19 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Defendant's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases BRL, including its subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim

that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of BRL from liability of any kind.

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

7. Except for the attorneys' fees, costs, and expenses to which Ruta and Conroy are entitled to collect pursuant to 31 U.S.C. § 3730(d), and conditioned on Defendant's timely payment of the full Settlement Amount pursuant to Paragraph 3 above, the Relators Ruta and Conroy, for themselves and their heirs, executors, representatives, successors, attorneys, partners, agents, third party beneficiaries, assigns, and any and all entities formerly, now, or in the future owned in whole or in part by Ruta or Conroy, or any of Ruta or Conroy's heirs, executors, representatives, successors, partners, agents, or assigns (together with Ruta and Conroy, the Ruta/Conroy Releasors") release BRL, its current and former parent corporations, direct and indirect subsidiaries, corporate predecessors, successors, affiliates, and divisions, and BRL's current and former owners, officers, directors, employees, shareholders, attorneys, other agents, successors, and assigns (collectively, the "BRL Releasees"), from any and all claims, rights, demands, suits, matters, issues, proceedings, liabilities, damages, losses, obligations, liens, judgments, and actions or causes of action of any kind or description, whether known or unknown, contingent or absolute, suspected or

unsuspected, disclosed or undisclosed, matured or unmatured, for damages, injunctive relief, or any other remedy against any and all of the BRL Releasees, jointly and severally , that the Ruta/Conroy Releasors, jointly and severally, may have or may gain or assert against the BRL Releasees, jointly and severally, from the beginning of time until the Effective Date of this Stipulation.

8. In consideration of the execution of this Stipulation by the Ruta and Conroy Relators and their release as set forth in Paragraph 7 above, the BRL Releasees, release the Ruta/Conroy Releasors from any and all claims, rights, demands, suits, matters, issues, proceedings, liabilities, damages, losses, obligations, liens, judgments, and actions or causes of action of any kind or description, whether known or unknown, contingent or absolute, suspected or unsuspected, disclosed or undisclosed, matured or unmatured, for damages, injunctive relief, or any other remedy against any and all of the Ruta/Conroy Releasors, jointly and severally, that the BRL Releasees, jointly and severally, may have or may gain or assert against the Ruta/Conroy Releasors, jointly and severally, from the beginning of time until the Effective Date of this Stipulation.

9. Except for the attorneys' fees, costs, and expenses to which Everett is entitled to collect pursuant to 31 U.S.C. § 3730(d), and conditioned on Defendant's timely payment of the full Settlement Amount pursuant to Paragraph 3 above, the Relator Everett, for himself and his heirs, executors, representatives, successors, attorneys, partners, agents, third party beneficiaries, assigns, and any and all entities formerly, now, or in the future owned in whole or in part by Everett, or any of Everett's heirs, executors, representatives, successors, partners, agents, or assigns (together with Everett, the Everett Releasors") release BRL, its current and former parent corporations, direct and indirect subsidiaries, corporate predecessors, successors, affiliates, and divisions, and BRL's current and former owners, officers, directors, employees, shareholders, attorneys, other agents, successors, and assigns (collectively, the "BRL Releasees"), from any and all claims, rights,

demands, suits, matters, issues, proceedings, liabilities, damages, losses, obligations, liens, judgments, and actions or causes of action of any kind or description, whether known or unknown, contingent or absolute, suspected or unsuspected, disclosed or undisclosed, matured or unmatured, for damages, injunctive relief, or any other remedy against any and all of the BRL Releasees, jointly and severally, that the Everett Releasors, jointly and severally, may have or may gain or assert against the BRL Releasees, jointly and severally, from the beginning of time until the Effective Date of this Stipulation.

10. In consideration of the execution of this Stipulation by the Everett Relators and their release as set forth in Paragraph 9 above, the BRL Releasees, release the Everett Releasors from any and all claims, rights, demands, suits, matters, issues, proceedings, liabilities, damages, losses, obligations, liens, judgments, and actions or causes of action of any kind or description, whether known or unknown, contingent or absolute, suspected or unsuspected, disclosed or undisclosed, matured or unmatured, for damages, injunctive relief, or any other remedy against any and all of the Everett Releasors, jointly and severally, that the BRL Releasees, jointly and severally, may have or may gain or assert against the Everett Releasors, jointly and severally, from the beginning of time until the Effective Date of this Stipulation.

11. As a condition for Relators' agreements herein, including dismissal of Relators' claims with prejudice, Defendant waives any right to challenge or assert any defense to the Relators' claims for a relator's share of the Settlement Amount, and agree that Relators and their attorneys are entitled to reasonable expenses, attorney's fees and costs pursuant to 31 U.S.C. § 3730(d); provided, however, that Defendant expressly reserves their right to challenge the amount and reasonableness of Relators' claims for attorney's fees, expenses, and costs. Relators and Defendant agree that this Court shall have continuing jurisdiction to issue orders with regard to any disputes

over the amounts for attorney's fees, expenses, and costs. They further agree that, should the parties be unable to reach an agreement on amounts, Relators each may file a motion for attorney's fees, expenses, and costs.

12. Notwithstanding the releases given in Paragraph 5 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

a. any liability arising under Title 26, United States Code (Internal Revenue Code);

b. any criminal liability;

c. except as explicitly stated in this Stipulation, any administrative liability, including but not limited to the mandatory or permissive exclusion from Federal healthcare 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) (permissive exclusion);

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 Stipulation; and

f. any liability of individuals.

13. Defendant shall be in default of this Stipulation if Defendant fails to make the required payments set forth in Paragraph 3 above on or before the due date for such payment, or if it fails to comply materially with any other term of this Stipulation ("Default"). The Government shall provide written notice to Defendant of any Default in the manner set forth in Paragraph 31 below. Defendant shall then have an opportunity to cure the Default within ten (10) calendar days

from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Settlement Amount, beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, Defendant shall agree to the entry of a consent judgment in favor of the United States against Defendant in the amount of the Settlement Amount, as attached hereto as Exhibit A. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against Defendant in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing Defendant by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Defendant shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Defendant shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Defendant shall not 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 relate to the Covered Conduct.

14. The Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; the Relators agree and confirm that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

15. Defendant agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as the Covered Conduct. 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), Tricare, or any state payer, related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare contractor, Tricare 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.

16. Defendant waives and shall not assert any defenses it 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action.

17. BRL having truthfully admitted to the conduct set forth in Paragraph 2 above (the "Admitted Conduct"), agrees that it shall not, through its attorneys, agents, officers, or employees, or through OPKO's attorneys, agents, officers or employees ("Covered Individuals"), make any public statement, including but not limited to any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Defendant or any Covered Individual shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 13 above, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify

Defendant, in writing, that it has determined that Defendant has made a Contradictory Statement. Upon receiving such notice from the Government, Defendant may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Defendant learns of a potential Contradictory Statement by a Covered Individual, Defendant must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Defendant for the purpose of this Stipulation, or whether Defendant adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Defendant and OPKO may raise defenses and/or assert affirmative claims or defenses in any proceeding brought by private and/or public parties, so long as doing so would not contradict or be inconsistent with the Admitted Conduct.

18. Defendant represents and warrants that it has reviewed its financial situation, that it is currently not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes it shall remain solvent following payment to the Government of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to BRL, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which BRL was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

19. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Defendant and/or OPKO commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of BRL's or OPKO's debts, or seeking to adjudicate BRL or OPKO as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for BRL or OPKO or for all or part of BRL's or OPKO's assets, Defendant agrees as follows:

a. Defendant's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Defendant shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Defendant's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Defendant is insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Defendant.

b. If any of Defendant's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the release in Paragraph 5 above. Defendant agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C.

§ 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Defendant shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) Defendant shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Defendant that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the date the Everett Complaint and the Ruta-Conroy Complaint were filed; and (iii) the Government has an undisputed, noncontingent, and liquidated allowed claim against Defendant in the amount of the Settlement Amount set forth in Paragraph 3 above and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding, and shall be allowed to offset the remaining unpaid balance of its claim from any amounts due and owing Defendant by any department, agency, or agent of the United States without seeking further authorization from any court under 11 U.S.C. § 362(a)(7).

c. Defendant acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

20. Defendant agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47m 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 Defendant, including its present or former officers, directors, employees, and agents in connection with:

(1) the matters covered by this Stipulation;

(2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;

(3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);

(4) the negotiation and performance of this Stipulation; and

(5) any payment Defendant makes to the United States pursuant to this Stipulation and any payment Defendant may makes to the Relators, including expenses, costs and attorneys' fees;

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

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendant shall identify and repay

by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Defendant from the United States. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Defendant's books and records and to disagree with any calculation submitted by Defendant or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Defendant, or the effect of any such Unallowable Costs on the amounts of such payments.

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

21. Upon receipt of the payment described in Paragraph 3 above, the United States and the Relators shall promptly sign and file Joint Stipulations of Dismissal pursuant to Fed. R. Civ. P. 41(a)(1)(A) related to the Ruta-Conroy Complaint, the Everett Complaint, and the Government Complaint. The dismissal shall be with prejudice as to Relators as to all claims against the Defendant. With respect to the United States, the dismissal shall be with prejudice as to the

Covered Conduct and without prejudice as to any other allegations. However, the Court shall retain jurisdiction over this Stipulation to enforce obligations pursuant to Paragraph 4 above.

22. This Stipulation 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 as otherwise provided herein.

23. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude the Relators from seeking to recover their expenses or attorneys' fees and costs from Defendant, pursuant to 31 U.S.C. § 3730(d).

24. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

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

26. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties.

27. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

28. This Stipulation is binding on Defendant's successor entities.

29. This Stipulation is binding on the Relators' successors, transferees, heirs, and assigns.

30. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

31. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Ellen Blain, Esq.
Assistant United States Attorney
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2743
Email: ellen.blain@usdoj.gov

TO DEFENDANT:

Eric Corngold, Esq.
Friedman Kaplan Seiler & Adelman LLP
7 Times Square
New York, NY 10036-6516
Phone: 212.833.1114
Email: ecorngold@fklaw.com

Jane Pine Wood
Chief Legal Counsel
BIOREFERENCE LABORATORIES, INC.
Mailing address: 481 Edward H. Ross, Elmwood Park, NJ 07407
Physical address: 475 Market Street, Elmwood Park, NJ 07407
jwood@BioReference.com
800-229-5227 x 7800

TO RELATOR EVERETT:
David A. Koenigsberg/Partner
Menz Bonner Komar & Koenigsberg LLP
One N. Lexington Ave., Suite 1550
White Plains, New York 10601
Phone: 914.949.0222, ext. 305
Email: dkoenigsberg@mbkklaw.com

James T. Ratner, Esq.
P.O. Box 449
Kingston, NY
Phone: 845.750.3293
Email: jamestratner@yahoo.com

TO RELATORS RUTA AND CONROY:
Jerome M. Marcus, Esq.
Jonathan Auerbach, Esq.
Marcus & Auerbach LLC
1121 N. Bethlehem Pike, Suite 60-242
Spring House, PA 19477
Phone: 215.885.2250
Email: jmarcus@marcusauerbach.com
auerbach@marcusauerbach.com

32. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: September 9, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: _____
Ellen Blain
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Tel.: (212) 637- 2743
Email: ellen.blain@usdoj.gov

DEFENDANT

Dated: September 8, 2020

BIO-REFRENCE LABORATORIES, INC.

By: _____
Geoff Monk, President

FRIEDMAN KAPLAN SEILER &
ADELMAN LLP

By: _____
Eric Corngold, Esq.
Friedman Kaplan Seiler & Adelman LLP
7 Times Square
New York, NY 10036-6516
Phone: 212.833.1114
Email: ecorngold@fklaw.com
Attorneys for Defendant

RELATOR

Dated: September __, 2020

By: _____
KREGG EVERETT
Relator

Dated: September 2, 2020

MENZ BONNER KOMAR &
KOENIGSBERG LLP

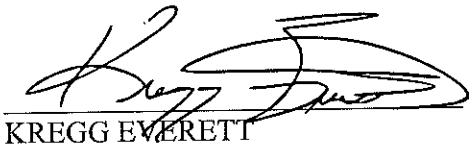
By: _____
David A. Koenigsberg/Partner
Menz Bonner Komar & Koenigsberg LLP
One N. Lexington Ave., Suite 1550
White Plains, New York 10601
Phone: 914.949.0222, ext. 305
Email: dkoenigsberg@mbkklaw.com

James T. Ratner, Esq.
P.O. Box 4491
Kingston, NY
Phone: 845.750.3293
Email: jamestratner@yahoo.com

Attorneys for Relator Kregg Everett

RELATOR

Dated: September __, 2020

By: 
KREGG EVERETT
Relator

Dated: September __, 2020

MENZ BONNER KOMAR &
KOENIGSBERG LLP

By: _____
David A. Koenigsberg/Partner
Menz Bonner Komar & Koenigsberg LLP
One N. Lexington Ave., Suite 1550
White Plains, New York 10601
Phone: 914.949.0222, ext. 305
Email: dkoenigsberg@mbkklaw.com

James T. Ratner, Esq.
P.O. Box 4491
Kingston, NY
Phone: 845.750.3293
Email: jamestratner@yahoo.com

Attorneys for Relator Kregg Everett

RELATOR

Dated: August 31, 2020

By: _____
SAMUEL RUTA
Relator

Dated: August 31, 2020

By: _____
BLAIR CONROY
Relator

Dated: August 31, 2020

MARCUS & AUERBACH LLC

By: _____
Jerome M. Marcus, Esq.
Jonathan Auerbach, Esq.
Marcus & Auerbach LLC
1121 N. Bethlehem Pike, Suite 60-242
Spring House, PA 19477
Phone: 215.885.2250
Email: jmarcus@marcusauerbach.com
auerbach@marcusauerbach.com

Attorneys for Relators Ruta and Conroy

SO ORDERED:

_____
HON. GEORGE B. DANIELS
UNITED STATES DISTRICT JUDGE

Dated: SEP 14 2020
New York, New York

EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et. al*, *ex rel.* KREGG EVERETT, Plaintiffs, v. GENPATH DIAGNOSTICS, BIO-REFERENCE LABORATORIES, INC., and CYTOMETRY SPECIALISTS, INC., Defendants.	**10 Civ. 4212 (GBD)**
UNITED STATES OF AMERICA *ex rel.* SAMUEL RUTA and BLAIR CONROY, Plaintiffs, v. BIO-REFERENCE LABORATORIES, INC., Defendant.	**11 Civ. 3850 (GBD)**
UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. BIO-REFERENCE LABORATORIES, INC., Defendant.	

JUDGMENT

Upon the consent of plaintiff the United States of America and defendant Bio-Reference Laboratories, Inc., it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of **$11,500,960.00, plus pre-judgment interest** at the rate of 1.25% per annum compounded annually from March 2, 2020 through the date on which this Judgment is entered, against Bio-Reference Laboratories, Inc.

Dated: September __, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: _____
Ellen Blain
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Tel.: (212) 637- 2743
Email: ellen.blain@usdoj.gov

Dated: September 8, 2020

FRIEDMAN KAPLAN SEILER &
ADELMAN LLP

By: _____
Eric Corngold, Esq.
Friedman Kaplan Seiler & Adelman LLP
7 Times Square
New York, NY 10036-6516
Phone: 212.833.1114
Email: ecorngold@fklaw.com
Attorneys for Defendant

Dated: New York, New York
September __, 2020

_____
HONORABLE GEORGE B. DANIELS
UNITED STATES DISTRICT JUDGE

EXHIBIT B

GUARANTY AGREEMENT

This Guaranty Agreement is entered into by and among OPKO Health Inc. ("OPKO") and the United States of America ("United States") (collectively the "Parties").

WHEREAS, the United States has conducted an investigation of Bio-Reference Laboratories, Inc. ("BRL") regarding violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* and the Anti-Kickback Statute (the "AKS"), 42 U.S.C. §§ 13320a-7b(b);

WHEREAS, the Government alleges that: (1) during the period 2009 through 2012, BRL fraudulently billed Medicare and Tricare for certain testing performed for hospital inpatients and listed on the Clinical Lab Fee Schedule ("CLFS"), 42 C.F.R. § 414 *et seq.*, which should have been paid by the hospitals themselves ("Inpatient Testing Covered Conduct"), and (2) during the period 2009 through 2012, BRL knowingly offered and paid remuneration, in the form of a percentage of the cost of electronic medical records transition software, to physicians based on the volume of business generated by those physicians in order to induce them to use BRL's services ("EMR Software Donation Covered Conduct"). This Inpatient Testing Covered Conduct and the EMR Software Donation Covered Conduct are referred to collectively as the "Covered Conduct";

WHEREAS, the Government, through the Office of the United States Attorney for the Southern District of New York, is filing a Notice of Election to Partially Intervene and a Complaint-In-Intervention in two pending *qui tam* actions in the United States District Court for the Southern District of New York: (1) *United States ex rel. Ruta, et al. v. Bio-Reference Laboratories, Inc.*, 11 Civ. 3850 (GBD); and (2) *United States, et al., ex rel. Kregg Everett v. Genpath Diagnostics, et al.*, 10 Civ. 4212 (GBD) (together, "the Relators' Actions");

WHEREAS, the United States, BRL, and the relators in the Relators' Actions wish to settle allegations related to the Inpatient Testing Covered Conduct and the EMR Software Donation Covered Conduct through the execution of a Stipulation and Order of Settlement and Dismissal (the "Stipulation") dated September __ 2020, and the Exhibits thereto, including this Guaranty Agreement;

WHEREAS, BRL has executed the Stipulation, incorporated by reference herein, wherein BRL promises to pay the United States $11,500,960.00 plus applicable interest (the "Settlement Amount") as set forth in Paragraph 3 of the Stipulation.

IT IS HEREBY AGREED that, in exchange for adequate consideration, the Parties shall undertake the following obligations:

TERMS AND CONDITIONS

1. Statement of Guaranty. Guarantor unconditionally guarantees the prompt payment, when due, of the full amount of all payments required to be made by BRL in accordance with the terms and provisions set forth in Paragraph 3 of the Stipulation.

2. Nature of Guaranty. The Guaranty set forth in Paragraph 1 of this Agreement constitutes a guaranty of payment of the full Settlement Amount by BRL as set forth in Paragraph 3 of the Stipulation, and shall not be affected by any event, occurrence or circumstance which might otherwise constitute a legal or equitable discharge or defense of a guarantor or surety (other than full and complete payment of the Settlement Amount). In the event that any payment by BRL pursuant to the Settlement Agreement is rescinded or must otherwise be returned by virtue of any action by any bankruptcy court, Guarantor shall remain liable hereunder with respect to such Settlement Amount as if payment had not been made. Guarantor agrees that the United States may resort to Guarantor for payment of any of the Settlement Amount, without regard to whether the United States shall have proceeded against any other person or entity primarily or secondarily obligated with respect to any of the Settlement Amount.

3. Acceleration. Guarantor agrees that, within ten days of receipt of written notice from the United States that BRL (i) has failed to make any payment required by the Stipulation, and (ii) has not cured its Default as provided for under Paragraph 13 of the Stipulation, Guarantor will be obligated to pay in full the amount then due under the Stipulation. Guarantor understands that the failure to adhere fully to the terms of this paragraph would be a material breach of this Guaranty Agreement. Notice under this paragraph shall be provided to the signatories below, including:

Steven Rubin
Executive Vice President, Administration
OPKO Health, Inc.
4400 Biscayne Blvd.
Miami, FL 33137
srubin@opko.com
(305) 575-4100

4. No Waiver; Cumulative Rights. No failure on the part of the United States to exercise, and no delay in exercising, any right, remedy or power hereunder shall operate as a waiver thereof, nor shall any single or partial exercise by the United States of any right, remedy or power hereunder preclude any other or future exercise of any right, remedy or power. Each and every right, remedy and power hereby granted to the United States or allowed by law or other agreement shall be cumulative and not exclusive of any other, and may be exercised by the United States from time to time.

5. Effective Date. This Guaranty Agreement shall become effective on the Effective Date, as defined in Paragraph 32 of the Stipulation.

6. Subrogation. Guarantor shall not exercise any subrogation rights it may acquire against BRL as a result of this Guaranty Agreement until all of the Settlement Amount to the United States has been paid in full.

7. Waiver of Notice. Guarantor waives notice of the acceptance of this Guaranty, presentment, demand, notice of dishonor, protest, and all other notices whatsoever.

8. Duration. This Guaranty shall continue in full force and effect until all of the Settlement Amount has been paid in full.

9. Entire Agreement. Each Party hereto represents and warrants that this Guaranty Agreement constitutes a valid and binding agreement enforceable against each Party in accordance with its terms. This Guaranty Agreement embodies the entire guaranty agreement between the Parties. There are no promises, terms, conditions or obligations other than those contained in this Guaranty Agreement. This Guaranty Agreement supersedes all previous communications, representations or agreements either verbal or written between Guarantor and the United States.

10. Severability. Should any one or more provisions of this Agreement be determined to be illegal, unenforceable, void or voidable, all other provisions shall remain in effect.

11. Assignment. No Party hereto may assign its rights, interest or obligations hereunder to any other person or entity without prior written consent of the other Party. The provisions of this Agreement shall be binding on the Parties hereto and their successors and assigns. This Agreement is to continue in full force and effect notwithstanding a change in the composition, ownership or corporate structure of Guarantor.

12. Miscellaneous. This Agreement shall not be amended except in a writing signed by all Parties. Each signatory hereto represents and warrants that he or she is authorized to execute and deliver this Agreement on behalf of the Party for whom he or she is purporting to act. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

13. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by and construed in accordance with federal common law. The Parties consent to the jurisdiction of the United States District Court for Southern District of New York in any action to enforce any term of this Agreement.

GUARANTOR

Dated: September 8, 2020

OPKO Health Inc.

By: _____
Steven Rubin, Executive Vice President, Administration

THE UNITED STATES OF AMERICA

Dated: September 9, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: _____
ELLEN BLAIN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2743
Email: ellen.blain@usdoj.gov