

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *ex rel.* JANE
DOE,

Plaintiff,

v.

FPR SPECIALTY PHARMACY, LLC; MEAD
SQUARE PHARMACY, INC.; CHRISTOPHER
K. CASEY; WILLIAM RUE; DR. DANIEL C.
ROTH; and DR. CATHERINE M. LAVIGNE,

Defendants.

No. 16 Civ. 5204 (PAE)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

FPR SPECIALTY PHARMACY, LLC; MEAD
SQUARE PHARMACY, INC.; CHRISTOPHER
K. CASEY; and WILLIAM RUE,

Defendants.

**STIPULATION AND ORDER OF
SETTLEMENT AND DISMISSAL
AS TO DEFENDANTS FPR
SPECIALTY PHARMACY, LLC;
MEAD SQUARE PHARMACY,
INC.; AND CHRISTOPHER K.
CASEY**

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, Geoffrey S. Berman, United States Attorney for the Southern District of New York; relator Jane Doe (“Relator”), by her authorized representatives; and defendants FPR Specialty Pharmacy, LLC (“FPR”), Mead Square Pharmacy, Inc. (“Mead Square”), and Christopher K. Casey (“Casey,” and together, the “FPR Defendants”), by their authorized representatives (together with the Government and Relator, the “Parties);

WHEREAS, on or about June 30, 2016, the Relator filed a complaint under the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, against the FPR Defendants and William Rue (“Rue,” and together the “Pharmacy Defendants”)¹ alleging, *inter alia*, that they violated the FCA by dispensing and selling by mail compounded prescription pharmaceutical preparations to customers covered by federal and state healthcare programs who were located in states in which the Pharmacy Defendants were not, or should not have been, licensed to do so, and that they dispensed and sold such prescription medications in a manner that violated the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b (the “Relator Complaint”);

WHEREAS, on or about January 29, 2018, the Relator filed an amended *qui tam* complaint against the same defendants, as well as Dr. Daniel C. Roth and Dr. Catherine M. LaVigne (the “Physician Defendants”), reiterating the allegations against the Pharmacy Defendants (but only with regard to patients covered by federal healthcare programs), and alleging that the Physician Defendants violated the AKS by accepting certain payments from the Pharmacy Defendants (the “Relator Amended Complaint”);

WHEREAS, on June 16, 2016, FPR filed articles of dissolution with the New York Secretary of State, and on or about March 27, 2020, Casey and Rue, the former members of FPR, executed a unanimous consent permitting either of them to execute settlement agreements on behalf of FPR;

¹ Relator’s original complaint was also brought on behalf of several states: the State of California, the State of Connecticut, the State of Florida, the State of Illinois, the State of Indiana, the State of Iowa, the State of New Jersey, the State of New Mexico, the State of New York, the State of Tennessee, the State of Texas, and the Commonwealth of Virginia (together, the “States”). The States consented to the dismissal of the claims on their behalf.

WHEREAS, the Government alleges that from 2011 to 2015 (the “Covered Period”):

- a. The Pharmacies sold a compounding prescription preparation known as “Focused Pain Relief,” an analgesic cream, to their mail-order customers around the country;
- b. Mead Square sold the preparation in question from 2011 until August 2013, and FPR sold it from August 2013 until 2015;
- c. The Pharmacy Defendants violated the FCA by dispensing and selling by mail compounded prescription pharmaceutical preparations to customers covered by federal healthcare programs who were located in states in which the pharmacies were not licensed to do so;
- d. The Pharmacy Defendants violated the FCA by not disclosing, in connection with their applications to become licensed mail-order pharmacies to customers in certain states, that they had previously sold prescription drugs to customers in those states without being licensed, which would likely have resulted in the rejection of their applications;
- e. The Pharmacy Defendants violated the FCA by not disclosing, in connection with their applications to become licensed mail-order pharmacies to customers in certain states, the relevant criminal history of Casey, the companies’ pharmacist-in-charge, despite specific questions asking them to do so, which would likely have resulted in the rejection of their applications;
- f. The Pharmacy Defendants violated the AKS (and thus the FCA) by not charging their customers who were covered by federal healthcare programs the required copay or coinsurance payments mandated by those programs for prescription drugs; and
- g. The Pharmacy Defendants violated the AKS (and thus the FCA) by entering into agreements with independent sales agents and distributors to solicit physicians to prescribe their pharmaceutical preparations, which provided that the pharmacies would pay the sales agents and distributors specific sums as sales commissions for each prescription prescribed by a physician assigned to the particular agent or distributor, and by actually paying their sales agents and distributors sales commissions on a per-prescription basis in accordance with these agreements.

The conduct described in this paragraph is the “Covered Conduct” for purposes of this Stipulation;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Intervene in Part and a Complaint-In-Partial-Intervention in the

above-referenced *qui tam* action (“Government Complaint”), in which it is asserting claims against the Pharmacy Defendants under the FCA and common law for the Covered Conduct, and declining to intervene against the Physician Defendants;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against the FPR Defendants in the Government Complaint and the Relator Amended Complaint, for the Covered Conduct;

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. The FPR Defendants admit, acknowledge and accept responsibility for the following conduct:
 - a. During the Covered Period, FPR and Mead Square, located in Victor, New York (together, the “Pharmacies”), sold a compounding prescription preparation known as “Focused Pain Relief,” an analgesic cream, to their mail-order customers around the country. Mead Square sold the preparation in question from 2011 until August 2013, and FPR sold it from August 2013 until 2015.
 - b. During the Covered Period, Casey was a part owner of FPR, as well as its vice president and pharmacist-in-charge; Casey was also the owner and president of Mead Square.
 - c. A substantial number of the Pharmacies’ customers who purchased Focused Pain Relief by mail order were covered by federal healthcare programs, including Tricare, Medicare, military veterans’ programs, federal workers’ compensation programs, and federal employee health-insurance programs. The Pharmacies submitted claims for payment to these federal healthcare programs in connection with their customers’ prescriptions for Focused Pain Relief, which were written by licensed physicians.
 - d. During the Covered Period, the Pharmacies sold prescriptions to customers covered by federal healthcare programs who were located in several states in which they were not licensed or no longer licensed by the

relevant state pharmacy boards to operate as an out-of-state mail-order pharmacy or otherwise sell prescription drugs to residents of those states.

- e. The Pharmacies did not disclose, in connection with their applications to state pharmacy boards, which were usually signed by Casey, when they had previously sold mail-order prescription drugs to residents of those states where the Pharmacies either were not licensed or had license applications pending but not yet issued.
- f. During the Covered Period, the Pharmacies often did not charge their customers who were covered by federal healthcare programs the required copays or coinsurance payments mandated by those programs for prescription drugs, in connection with their sales of Focused Pain Relief to those customers.
- g. From 2012 until mid-2014, the Pharmacies entered into agreements with independent sales agents and distributors to solicit physicians to prescribe Focused Pain Relief. These agreements generally provided that the Pharmacies would pay the sales agents and distributors specific sums as sales commissions for each prescription of Focused Pain Relief prescribed by a physician assigned to the particular agent or distributor. The Pharmacies actually paid their sales agents and distributors sales commissions on a per-prescription basis, in accordance with these agreements.

3. The FPR Defendants agree to pay and the Government agrees to accept the sum of three hundred sixty-five thousand dollars (\$365,000) (the “Settlement Amount”). The FPR Defendants are jointly and severally responsible for paying the Settlement Amount. The FPR Defendants shall pay the Settlement Amount within fourteen calendar days from the Effective Date (defined in Paragraph 33 below) 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. The Settlement Amount constitutes restitution to the United States.

4. The FPR Defendants agree to cooperate fully and truthfully with the United States’ investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, the FPR Defendants shall encourage, and agree not to impair, the cooperation of their 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. The FPR Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

5. Subject to the exceptions in Paragraphs 11 and 18 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon the FPR Defendants' 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 the FPR Defendants, including their subsidiaries and corporate predecessors, successors and assigns (for FPR and Mead Square), and their successors, heirs, and assigns (for Casey), 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 the FPR Defendants other than Casey from liability of any kind.

6. In consideration of the obligations of the FPR Defendants in this Stipulation and the Integrity Agreement ("IA"), entered into between the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG-HHS") and the FPR Defendants, and conditioned upon the FPR Defendants' 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 the FPR Defendants 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 11 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude the FPR Defendants 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 11, below.

7. The FPR Defendants fully and finally release 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 the FPR Defendants have 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.

8. Conditioned on the FPR Defendants' timely payment of the full Settlement Amount pursuant to Paragraph 3 above, the Relator, for herself and her heirs, successors, attorneys, agents, and assigns, releases the FPR Defendants, including their subsidiaries and corporate predecessors, successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents (for FPR and Mead Square), and their successors, heirs, assigns, attorneys, and other agents (for Casey), from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has

against the FPR Defendants related to or arising from the Relator Complaint or the Relator Amended Complaint; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover, and Relator does not release herein, her reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

9. As a condition for Relator's agreement herein, including dismissal of relator's claims with prejudice, the FPR Defendants agree that Relator and her attorneys are entitled to reasonable expenses, attorney's fees and costs pursuant to 31 U.S.C. § 3730(d); provided, however, that the FPR Defendants expressly reserve their right to challenge the amount and reasonableness of Relator's claim for attorneys' fees, expenses, and costs. Relator and the FPR Defendants agree that the Court shall have continuing jurisdiction to issue orders with regard to any disputes over the amounts for expenses, attorney's fees, and costs. They further agree that, should the parties be unable to reach an agreement on amounts, Relator may file a motion for attorney's fees, costs, and expenses within 60 days of the Effective Date, or within such longer period that is agreed by the Relator and the FPR Defendants and approved by the Court.

10. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 8 above, the FPR Defendants, including their subsidiaries and corporate predecessors, successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents (for FPR and Mead Square), and their heirs, assigns, attorneys, and other agents (for Casey), release the Relator and her successors, heirs, assigns, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the FPR Defendants have against Relator related to or arising from the Relator Complaint or the Relator Amended Complaint.

11. 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 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 Stipulation; and
- f. any liability of individuals other than Casey.

12. The FPR Defendants shall be in default of this Stipulation if they fail to pay the Settlement Amount on or before the required date, or if they fail to comply materially with any other term of this Stipulation that applies to them (“Default”). The Government shall provide written notice to the FPR Defendants of any Default in the manner set forth in Paragraph 32 below. The FPR Defendants 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 Consent Judgment Amount (defined below), beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, the FPR Defendants shall agree to the entry of a consent judgment in favor of the Government and against the Pharmacy Defendants, jointly and severally, in the amount of five million four hundred twenty-seven thousand two hundred seventy-six dollars (\$5,427,276) (the “Consent Judgment

Amount”), a copy of which is attached hereto as Exhibit A (the “Consent Judgment”). In the event that the Pharmacy Defendants have paid any amounts to the Government prior to the Uncured Default, they may, within ten (10) calendar days of the Uncured Default, execute and deliver to the United States a substitute consent judgment that includes only the amount of the unpaid portion of the Consent Judgment Amount. In the event that only the FPR Defendants, but not Rue, have an Uncured Default, the FPR Defendants shall, within ten (10) calendar days of the Uncured Default, execute and deliver to the United States a substitute consent judgment against the FPR Defendants that includes only the amount of the unpaid portion of the Consent Judgment Amount. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against the FPR Defendants in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Consent Judgment Amount from any amounts due and owing the FPR Defendants 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. The FPR Defendants 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, the FPR Defendants 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, the FPR Defendants 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.

13. The FPR Defendants, having truthfully admitted to the conduct set forth in Paragraph 2 hereof (the “Admitted Conduct”), agree they shall not, through their attorneys,

agents, officers, or employees, 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 the FPR Defendants, their attorneys, agents, officers, or employees, shall constitute a violation of this Consent Order, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 11 hereof, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify the FPR Defendants that it has determined that any or all of them have made a Contradictory Statement. Upon receiving notice from the Government, the FPR Defendants may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If the FPR Defendants learn of a potential Contradictory Statement by their attorneys, agents, officers, or employees, the FPR Defendants 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 the FPR Defendants for the purpose of this Consent Order, or whether the FPR Defendants adequately repudiated a Contradictory Statement to cure a violation of this Consent Order, shall be within the sole discretion of the Government. Consistent with this provision, the FPR Defendants 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.

14. The Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms 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. The FPR Defendants agree that they waive and shall not seek payment for any of the healthcare billings covered by this Stipulation from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

16. The FPR Defendants waive and shall not assert any defenses they 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. The FPR Defendants represent and warrant that they have reviewed their respective financial situations, that they are currently not insolvent as such term is defined in 11 U.S.C. § 101(32). 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 the FPR Defendants, 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 the FPR Defendants were or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

18. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, the FPR Defendants, or any of them, commence 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 any or all of the FPR Defendants' debts, or seeking to adjudicate any or all of the FPR Defendants as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for any or all of the FPR Defendants or for all or part of their assets, the FPR Defendants agree as follows:

- a. The FPR Defendants' obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and the FPR Defendants, or any of them, shall not argue or otherwise take the position in any such case, action, or proceeding that (i) their obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) they were 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 them.
- b. If any of the FPR Defendants' 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 any or all of the FPR Defendants for the claims that would otherwise be covered by the release in Paragraph 5 above. The FPR Defendants agree 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 the FPR Defendants shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) the FPR Defendants 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 the FPR Defendants that the release has been rescinded pursuant to this paragraph, except to the extent such defenses were available on June 30, 2016; and (iii) the Government has a valid claim against the FPR Defendants in the amount of the Consent Judgment Amount 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.

- c. The FPR Defendants acknowledge that the agreements in this paragraph are provided in exchange for valuable consideration provided in this Stipulation.

19. The FPR Defendants have provided sworn financial disclosure statements and other information and materials relevant to their ability to make payments to resolve this matter (“Financial Information”) to the United States and the United States has relied on the accuracy and completeness of that Financial Information in reaching this Stipulation. The FPR Defendants warrant that the Financial Information is complete, accurate, and current. If the United States learns of asset(s) in which any or all of the FPR Defendants had an interest at the time of this Stipulation that were not disclosed in the Financial Information, or if the United States learns of any misrepresentation by any or all of the FPR Defendants on, or in connection with, the Financial Information, and if such nondisclosure or misrepresentation changes the net worth of any of the FPR Defendants as reflected in the Financial Information by fifty thousand dollars (\$50,000) or more, the United States may at its option: (a) rescind this Stipulation and reinstate its suit against the FPR Defendants based on the Covered Conduct, or (b) let the Stipulation stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of the FPR Defendants previously undisclosed. The FPR Defendants agree 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 attorneys’ fees and expenses.

20. In the event that the United States, pursuant to Paragraph 18 above (concerning disclosure of assets) opts to rescind this Stipulation, the FPR Defendants agree 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 180 calendar days of written notification to the FPR Defendants that this

Stipulation has been rescinded, and (b) are based on the Covered Conduct, except to the extent these defenses were available on June 30, 2016.

21. 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), any carrier or payer for any federal healthcare program, including Tricare, military veterans' programs, federal workers' compensation programs, and federal employee health-insurance programs, or any state payer, related to the Covered Conduct; and the FPR Defendants agree not to resubmit to any Medicare contractor, any carrier or payer for any federal healthcare program, or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

22. The FPR Defendants agree 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 the FPR Defendants, including their 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) the FPR Defendants' 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) and the IA;
 - (4) the negotiation and performance of this Stipulation and the IA; and
 - (5) any payment the FPR Defendants make to the United States pursuant to this Stipulation and any payment the FPR Defendants

may make to the Relator, 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 (FEHBP) (hereinafter referred to as "Unallowable Costs").

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the FPR Defendants, and the FPR Defendants 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, the FPR Defendants 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 the FPR Defendants from the United States. The FPR Defendants agree that the United States, at a minimum, shall be entitled to recoup from them 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 the FPR Defendants' books and records and to disagree with any calculation submitted by them or any of their subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by the FPR Defendants, 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 the FPR Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

23. 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.

24. 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 Relator from seeking to recover her expenses or attorneys' fees and costs from the FPR Defendants, pursuant to 31 U.S.C. § 3730(d).

25. 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.

26. 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.

27. 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.

28. 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.

29. This Stipulation is binding on the successor entities of Defendants FPR and Mead Square, and the successors, transferees, heirs, and assigns of Defendant Casey.

30. This Stipulation is binding on the Relator's successors, transferees, heirs, and assigns.

31. 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.

32. 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:

Jean-David Barnea
Assistant United States Attorney
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, NY 10007
Email: Jean-David.Barnea@usdoj.gov

TO THE FPR DEFENDANTS:

Robert G. Trusiak, Esq.
Trusiak Law
300 International Drive, Suite 100
Williamsville, NY 14221
Email: robert@trusiaklaw.com

-and-

David Rothenberg, Esq.
Rothenberg Law
45 Exchange Street, Suite 800
Rochester, NY 14614
Email: drothenberg@geigroth.com

TO RELATOR:

Randall M. Fox, Esq.
Kirby McInerney LLP
250 Park Avenue, Suite 820
New York, NY 10177
Email: rfox@kmlp.com

33. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the “Effective Date”).

34. Nothing in this Stipulation affects the Relator’s claims against the Physician Defendants.

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York
March 30, 2020

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: 

JEAN-DAVID BARNEA
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Tel.: (212) 637-2679
Fax: (212) 637-2686

Attorney for the United States of America

Dated: Washington, D.C.
March 30, 2020



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Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

RELATOR

Dated: New York, New York
March 26, 2020

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THE FPR DEFENDANTS

Dated: Victor, New York
March 7, 2020

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Christopher K. Casey
Member

Dated: Victor, New York
March 7, 2020

MEAD SQUARE PHARMACY, INC.

By: Christopher K. Casey
Christopher K. Casey
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Dated: Victor, New York
March __, 2020

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SO ORDERED:

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HON. PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE

Dated: April 2, 2020