GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
Attorney for the United States of America
By: JEAN-DAVID BARNEA
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel. No.: (212) 637-2679

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.	**COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA**

1. 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, having filed a notice of partial intervention against defendants FPR Specialty Pharmacy, LLC

("FPR"), Mead Square Pharmacy, Inc. ("Mead Square"), Christopher K. Casey ("Casey"), and William Rue ("Rue," and together the "Defendants") pursuant to 31 U.S.C. § 3730(b)(4), alleges for its complaint-in-intervention as follows:

PRELIMINARY STATEMENT

2. This is a civil fraud suit brought by the United States against the Defendants under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), to recover damages sustained by, and penalties owed to the United States as the result of the Defendants' having submitted false claims to the Government and having violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS").

3. Specifically, Defendants violated the FCA by submitting claims to federal healthcare programs for reimbursement of a compounded prescription preparation known as "Focused Pain Relief" to program beneficiaries in which FPR and Mead Square were not licensed to dispense such drugs, or would not have been licensed to do so had they provided truthful information to the state pharmacy boards regarding their prior unauthorized sales in those states and regarding Casey's criminal record.

4. Further, Defendants violated the AKS, and thus the FCA, by submitting claims to federal healthcare programs for reimbursement of prescriptions of Focused Pain Relief to program beneficiaries under corporate policies of charging patients co-payments substantially below the mandated co-payments required by the federal healthcare programs, without individualized consideration of the patients' financial circumstances.

5. Finally, Defendants violated the AKS, and thus the FCA, by submitting claims to federal healthcare programs for reimbursement of prescriptions of Focused Pain Relief to program beneficiaries where the independent distributors and sales representatives promoting

this preparation to the prescribing physicians were compensated by per-prescription commissions.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the claim in this action pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C §§ 1331 and 1345.

7. Venue lies in this District on pursuant to 28 U.S.C. § 1391(b)(2).

PARTIES

8. Plaintiff is the United States of America on behalf of its agencies the U.S. Department of Defense ("DoD"), the U.S. Department of Health and Human Services ("HHS"), the U.S. Department of Labor ("DOL"), and the Office of Personnel Management ("OPM"). The United States filed its notice of partial intervention in this action on February 7, 2020.

9. Defendant Mead Square is a New York corporation with a principal place of business at 53 Main Street, in Victor, New York. Mead Square operates a retail pharmacy at that location. From 2011 until August 2013, Mead Square also operated as a compounding mail-order pharmacy that compounded, dispensed, and billed for "Focused Pain Relief." Mead Square dispensed this drug in many states around the country, including in this District.

10. Defendant FPR was a New York limited liability company that had its principal places of business at 7910 Rae Boulevard and 53 Main Street, in Victor, New York. On June 16, 2016, FPR filed articles of dissolution with the New York Secretary of State. FPR was a compounding mail-order pharmacy that, from August 2013 until 2015, compounded, dispensed, and billed for a custom topical prescription pain medication called "Focused Pain Relief." FPR dispensed this drug in many states around the country.[1]

[1] Compounding is the practice in which a licensed pharmacist or physician creates a medication with specific ingredients tailored to meet the needs of an individual patient.

11. Defendant Casey is an individual who resides in Victor, New York. Casey is a licensed pharmacist in New York State. Casey was a part owner of FPR, as well as its vice president and pharmacist-in-charge. Casey is also the owner and president of Mead Square.

12. Defendant Rue is an individual who resides in Victor, New York. Rue was a part owner and the president/CEO of FPR and was an employee of Mead Square.

FACTS

I. Applicable Statutory and Regulatory Scheme

A. Federal Healthcare Programs

a. TRICARE

13. TRICARE is a managed health care program established by DoD. *See* 10 U.S.C. § 1071 *et seq.* TRICARE provides health care benefits to eligible beneficiaries, which include active duty service members, retired service members, and their dependents.

14. TRICARE includes a pharmacy benefits program for its beneficiaries, which covers the cost of certain prescription drugs, subject to cost-sharing payments by the beneficiaries. *See* 10 U.S.C. § 1074g; 32 C.F.R. § 199.21(i).

15. In order for a pharmacy to receive payments from TRICARE for dispensing prescription drugs to a beneficiary, it "must meet the applicable requirements of state law in the state in which the pharmacy is located." 32 C.F.R. § 199.6(d)(3). It must also enter into a participation agreement in which it agrees to comply with applicable rules, including collecting the necessary cost-sharing payments from beneficiaries. *Id.* § 199.6(a)(13)(ii), (iv).

16. During the relevant period, TRICARE contracted the performance of some of its prescription benefits with Express Scripts Inc. ("ESI"), a commercial pharmacy benefits manager. Mead Square and FPR both entered into Provider Agreements with ESI. In these

Provider Agreements, Mead Square and FPR promised to: (i) be bound by and comply with all applicable "laws, rules and regulations including, but not limited to, fraud, waste, and abuse laws and applicable state boards of pharmacy's . . . laws, rules and regulations . . . that are necessary to allow [them] to dispense Covered Medications to Members"; (ii) collect from patients applicable TRICARE co-payments and not waive or discount co-payments unless directed to do so by ESI; and (iii) comply with all state and federal kickback laws.

b. Medicare

17. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See id.* §§ 426, 426A. Medicare is administered by HHS's Centers for Medicare & Medicaid Services ("CMS"). The Medicare program includes coverage for prescription drugs through Part D. *See id.* § 1395w-102.

18. CMS contracts with private companies ("Part D plan sponsors") to administer prescription drug plans. *See* 42 U.S.C. § 1395w-112. These plans include cost-sharing payments by beneficiaries for certain drugs. *See, e.g.*, *id.* § 1395w-102(b)(2); 42 C.F.R. § 423.104(d)(2), (4).

19. Pursuant to CMS regulations, Part D plan sponsors must agree to comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act and the anti-kickback statute." 42 C.F.R. § 423.505(h)(1) (citations omitted).

20. Part D plan sponsors, in turn, subcontract with pharmacies to provide drugs to Medicare Part D beneficiaries. These subcontracts obligate the participating pharmacies to

comply with "all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(4)(iv).

21. A pharmacy must be a "licensed pharmacy" in order to participate in Medicare Part D. 42 C.F.R. § 423.100.

22. Moreover, pharmacies submitting Medicare Part D claims must certify "that the claims data [they] submit[] [for reimbursement] are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

c. Federal Employees' Compensation Act

23. The Federal Employees' Compensation Act, 5 U.S.C. § 8101 *et seq.* ("FECA"), provides for the payment of workers' compensation benefits, including medical benefits, to federal employees and others. *See* 20 C.F.R. § 10.0. FECA is administered by DOL's Office of Workers' Compensation Programs. *See id.* § 1.2(a). Benefits available under FECA include prescription drugs, which do not require co-payments or other cost-sharing by beneficiaries. *See, e.g.*, *id.* § 10.809.

24. All participating FECA providers, including pharmacies, must "certify that they satisfy all applicable Federal and State licensure and regulatory requirements that apply to their specific provider or supplier type," and "must maintain documentary evidence indicating that [they] satisf[y] those requirements." 20 C.F.R. § 10.800(a).

25. Providers submitting requests for payment under FECA thereby "signif[y] that the service for which reimbursement is sought was performed as described, necessary, appropriate and properly billed in accordance with accepted industry standards." 20 C.F.R. § 10.801(d).

d. Federal Employee Health Benefit Program

26. The Federal Employee Health Benefit Program ("FEHBP") is a federally funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. *See* 5 U.S.C. § 8901 *et seq.* OPM administers this program and contracts with various health insurance carriers to provide services to FEHBP members. *See id.* §§ 8902, 8909(a). Funds for the FEHBP are maintained in the Employees Benefits Fund, which OMB administers. *See id.* § 8909(a).

27. The Employees Benefits Fund—which the United States Treasury holds and invests—is the source of all relevant payments to the insurance carriers for services rendered to its members. *See id.* § 8909.

28. FEHBP plans are operated by private insurers and generally require that drugs be dispensed to beneficiaries only by licensed pharmacies.

29. The AKS does not apply to claims submitted to FEHBP. *See* 42 U.S.C. § 1320-7b(f).

B. State Pharmacy Laws

30. States generally require pharmacies dispensing or selling drugs in or into that state, including by mail, to be licensed by the state. For example, under Texas law:

> (a) A person may not operate a pharmacy in this state unless the pharmacy is licensed by the [Texas Board of Pharmacy].
>
> (b) A pharmacy located in another state may not ship, mail, or deliver to this state a prescription drug or device dispensed under a prescription drug order, or dispensed or delivered as authorized by [the rules governing compounded or prepackaged drugs], unless the pharmacy is licensed by the board or is exempt under [rules permitting isolated instances of dispensing within the state].

Tex. Occupations Code § 560.001; *see* Del. Code, tit. 24, § 2526 *et seq.*

31. States each have processes for pharmacies to apply to become licensed in the state, and in some cases a separate application process and rules for out-of-state mail-order pharmacies. *See, e.g.*, Tex. Admin. Code § 291.101 *et seq.*; Del. Code, tit. 24, § 2545 *et seq.*

32. States generally consider it material in reviewing applications for out-of-state pharmacy licenses whether the applying pharmacy has previously dispensed or sold prescription drugs without a license in the state. For example, on or about February 11, 2014, the North Carolina Board of Pharmacy denied FPR's application to become a licensed out-of-state pharmacy because FPR had been shipping prescription drugs into the state without being licensed.

33. Many of the application forms to become a licensed pharmacy in a given state include questions about the criminal history of the applying pharmacy's principals. For example, during the relevant timeframe, the Delaware Board of Pharmacy asked applicants whether "any of the owners, corporate officers, pharmacists or unregistered employees listed on th[e] application [had] ever been convicted of or entered a plea of guilty or *nolo contendere* (no contest) to any felony, misdemeanor or any other criminal offense, including any offense for which they have received a pardon, in any jurisdiction."

C. The False Claims Act and Anti-Kickback Statute

34. A defendant violates the FCA when it "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B).

35. The statute defines "knowing," to include reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1)(A).

36. The AKS makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . any good, . . . service, or item 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).

37. The AKS applies to remuneration paid to, among others, independent distributors and sales agents, and patients. Specifically, it is a violation of the AKS for a healthcare provider, including a pharmacy, to routinely waive or reduce co-payments or other cost-sharing by beneficiaries of federal healthcare programs for reasons other than the genuine individual financial hardship or particular beneficiaries. Such co-payments are intended to minimize government healthcare costs by incentivizing beneficiaries to be better health care consumers by selecting services because they are medically necessary and cost effective.

38. It is also a violation of the AKS for a healthcare provider, including a pharmacy, to pay independent distributors or sales agents based on the volume of their sales. *See* 42 C.F.R. § 1001.952(d).

39. The submission of claims for federal healthcare services rendered in violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g).

II. Defendants Compounded and Sold "Focused Pain Relief" in Violation of the FCA and AKS

40. In 2011, Casey and Rue began selling a compounding prescription preparation known as "Focused Pain Relief," an analgesic cream, to mail-order customers around the country through Mead Square.

41. Casey and Rue created FPR, which shared a facility and employees with Mead Square, to operate the mail-order sale of Focused Pain Relief. FPR sold the preparation from August 2013 until 2015.

42. A substantial number of the pharmacies' customers who purchased Focused Pain Relief by mail order were covered by federal healthcare programs, including TRICARE, Medicare, FECA, and FEHBP. FPR and Mead Square submitted claims for payment to these federal healthcare programs in connection with their customers' prescriptions for Focused Pain Relief.

43. As explained below, nearly all of the sales of Focused Pain Relief by FPR and Mead Square to beneficiaries of federal healthcare programs were made in violation of the FCA and/or the AKS.

A. The Defendants Sold "Focused Pain Relief" to Beneficiaries in States Where They Were Not Licensed

44. Mead Square and FPR sold a substantial amount of Focused Pain Relief to customers in states where the pharmacies were not licensed, not yet licensed, in which their license applications were pending, or in which their licenses had expired.

45. For example, Mead Square and FPR sold approximately $468,876 worth of Focused Pain Relief to federal healthcare beneficiaries located in Texas between June 25, 2012, and January 3, 2014. However, FPR was not licensed as an out-of-state pharmacy in Texas until January 13, 2014, and Mead Square was not licensed as an out-of-state pharmacy in Texas at all during the relevant time period.

46. Casey and Rue knew that Mead Square and FPR sought reimbursement from federal healthcare programs for prescriptions to beneficiaries in states where the pharmacies were not licensed.

47. When Defendants knowingly submitted claims for reimbursement for prescriptions of Focused Pain Relief sold in states where they were not licensed, those claims were false.

B. The Defendants Sold "Focused Pain Relief" to Beneficiaries in States Where They Did Not Disclose Substantial Unauthorized Pre-License Sales in Their Pharmacy Board Applications

48. When Mead Square and FPR applied for licenses to become out-of-state pharmacies in various states, they did not reveal that, in many cases, they had sold substantial amounts of prescription drugs to residents of those states before submitting their applications or receiving their licenses.

49. One state's pharmacy board, the North Carolina Board of Pharmacy, discovered—although FPR did not disclose it—that FPR had previously sold prescription drugs to residents of that state without a license. Thus, on or about February 11, 2014, the board denied FPR's application to become a licensed out-of-state pharmacy.

50. Several other states in which FPR or Mead Square had sold substantial amounts of Focused Pain Relief before submitting their applications or receiving their licenses awarded the pharmacies licenses without knowing of their improper pre-license sales. These states included Texas, Virginia, and Tennessee.

51. FPR and Mead Square thus obtained licenses from the relevant state pharmacy boards under false pretenses. Many of the applications at issue were signed by Casey personally.

52. FPR and Mead Square thereafter sold substantial amounts of Focused Pain Relief to residents of those states, including beneficiaries of federal healthcare programs, although their applications for licenses would likely have been rejected had they accurately disclosed their pre-license sales.

53. When Defendants knowingly submitted claims for reimbursement for prescriptions of Focused Pain Relief sold in states where they would not have been licensed if they had provided truthful information to the state pharmacy board about their prior sales in that state, those claims were false.

C. The Defendants Sold "Focused Pain Relief" to Beneficiaries in States Where They Did Not Disclose Casey's Criminal Record on Their Pharmacy Board Applications

54. Many of the states in which Mead Square and FPR were licensed required pharmacies, as part of the application process, to answer questions regarding whether certain officers or employees of the pharmacies had a criminal record.

55. Casey had pled guilty to reckless driving, a misdemeanor, in 1978, and to a criminal violation in 2001, both in New York state courts.

56. While FPR and Mead Square disclosed these criminal records to certain states as part of their license applications, the pharmacies did not disclose them to other states, including Colorado, Delaware, Michigan, and New York. Their applications to these states' pharmacy boards falsely stated that there were no criminal convictions associated with the pharmacies' management.

57. FPR and Mead Square thus obtained licenses from the relevant state pharmacy boards under false pretenses. Many of the applications at issue were signed by Casey personally.

58. FPR and Mead Square thereafter sold substantial amounts of Focused Pain Relief to residents of those states, including beneficiaries of federal healthcare programs, although had the states' pharmacy boards known that FPR and Mead Square had lied about Casey's criminal history on the pharmacies' applications, they would likely have denied the applications.

59. When Defendants knowingly submitted claims for reimbursement for prescriptions of Focused Pain Relief sold in states where they would not have been licensed if

the state pharmacy board knew they had provided untruthful answers to questions about Casey's criminal history, those claims were false.

D. The Defendants Routinely Charged Beneficiaries of Federal Healthcare Programs Dramatically Reduced Co-Payments and Cost-Sharing Payments for "Focused Pain Relief"

60. Because the prescription ingredients used in preparing Focused Pain Relief were expensive, the co-payments and other cost-sharing payments for patients purchasing this compounded preparation were often quite large, frequently in the hundreds of dollars per prescription.

61. In order to induce them to purchase Focused Pain Relief, FPR and Mead Square regularly did not charge their customers, including beneficiaries of federal healthcare programs, the correct co-payments or other cost-sharing payments. The pharmacies made these reductions without consideration of their customers' individualized financial circumstances. This resulted in increased revenues for FPR and Mead Square, as intended.

62. FPR and Mead Square initially offered reduced flat-fee co-payments (as low as $15 or $30 per prescription) to patients of particular physicians, including patients who were federal healthcare beneficiaries.

63. FPR later instituted across-the-board flat co-payments of $50 for new prescriptions and $30 per refill for all patients, including federal healthcare beneficiaries.

64. When Defendants knowingly submitted claims for reimbursement for prescriptions of Focused Pain Relief for beneficiaries of federal healthcare programs (other than FEBHP) for which FPR and Mead Square charged improperly reduced co-payments or cost-sharing payments without notifying the programs, those claims were false.

E. FPR Compensated the Independent Distributors and Sales Representatives Who Promoted "Focused Pain Relief" by Paying Them Per-Prescription Commissions

65. From 2012 until mid-2014, FPR entered into Distributor Agreements with pharmaceutical distributors to market and promote Focused Pain Relief to physicians around the country. FPR required the distributors to entered into Independent Sales Representative Agreements with independent sales representatives on a form agreement provided by FPR to market and promote Focused Pain Relief to physicians within their assigned territories under the distributors' supervision.

66. In the Distributor Agreements, FPR agreed to pay the distributors compensation for their work, and in the Independent Sales Representative Agreements, the distributors agreed to pay the sales representatives for their work according to FPR's instructions. The compensation in each of these agreements was in the form of commissions paid in a dollar amount per prescription solicited. Many of the Distributor Agreements were signed by Rue personally.

67. For example, in some of the Distributor Agreements, FPR paid the distributor "at the rate of $100.00 per billable and paid prescription solicited by Distributor or an independent sales representative of Distributor." Other Distributor Agreements varied the amount of per-prescription compensation based on the number of "Qualified Prescriptions" per month (with higher per-prescription rates for months with more prescriptions) solicited by the distributor or its agents. In certain contracts, Qualified Prescriptions were defined as prescriptions for which FPR was paid more than a certain dollar threshold, with prescriptions in which FPR received less than the threshold not counting towards the commission.

68. In many of the Independent Sales Representative Agreements, the distributors paid the sales representatives, again as required by FPR, a flat rate per prescription solicited (for

example, $50 per prescription) or a variable per-prescription rate depending on the number of Qualified Prescriptions solicited per month.

69. FPR actually paid its distributors per-prescription commissions according to the Distributor Agreements, and the distributors (or in some cases FPR directly) actually paid the sales representatives per-prescription commissions according to the Independent Sales Representative Agreements. Defendants did this in order to increase their sales of Focused Pain Relief and increase their revenues from such sales.

70. Casey and Rue knew that it was illegal to submit claims to federal healthcare programs for claims in which the submitting pharmacy compensated independent distributors and/or sales representatives with per-prescription commissions.

71. When Defendants knowingly submitted claims for reimbursement for prescriptions of Focused Pain Relief for beneficiaries of federal healthcare programs (other than FEBHP) for which FPR and Mead Square paid distributors and sales representatives per-prescription commissions without notifying the programs, those claims were false.

F. Defendants' False Claims Were Material to the Federal Healthcare Programs

72. Federal healthcare programs do not reimburse claims for prescription drugs dispensed by pharmacies that are not licensed in the relevant states or that obtained their state licenses under false pretenses, or (with respect to healthcare programs other than FEHBP) claims that are tainted by kickbacks.

73. Defendants' false statements and omissions regarding their failure to comply with these requirements were material to the decisions of the federal healthcare programs to reimburse FPR and Mead Square for the prescriptions at issue.

CLAIMS FOR RELIEF

COUNT ONE
(Violation of 31 U.S.C. § 3729(a)(1)(A))

74. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

75. FPR and Mead Square submitted claims to federal healthcare programs for reimbursement for Focused Pain Relief for beneficiaries who were located in states where the relevant pharmacy was not licensed at the time the claim was submitted.

76. FPR and Mead Square submitted claims to federal healthcare programs for reimbursement for Focused Pain Relief for beneficiaries who were located in states where the relevant pharmacy was licensed, but had not disclosed to the state pharmacy board that it had previously made substantial unauthorized sales of Focused Pain Relief to customers in that state, and would likely not have become licensed in that state had it done so.

77. FPR and Mead Square submitted claims to federal healthcare programs for reimbursement for Focused Pain Relief for beneficiaries who were located in states where the relevant pharmacy was licensed, but had not disclosed Casey's criminal record to the state pharmacy board, and would likely not have become licensed in that state had it revealed that it did not truthfully answer the relevant question or questions on the application.

78. By submitting claims for reimbursement to federal healthcare programs for prescriptions of Focused Pain Relief in states where FPR and Mead Square were not licensed, or would not be licensed had they provided truthful information to the state pharmacy boards, Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States.

79. FPR and Mead Square submitted claims to federal healthcare programs for reimbursement for Focused Pain Relief for beneficiaries from which the relevant pharmacy had not collected the appropriate co-payment or other cost-sharing payment and had not individually analyzed the beneficiary's financial circumstances.

80. It is a violation of the AKS for a healthcare provider to routinely waive the co-payments or other cost-sharing payments of beneficiaries of federal healthcare programs without individualized consideration of each beneficiary's financial circumstances.

81. FPR and Mead Square submitted claims to federal healthcare programs for reimbursement for Focused Pain Relief for beneficiaries whose prescribing physicians were the recipients of marketing communications and materials from distributors and independent sales agents who were compensated by per-prescription commissions.

82. It is a violation of the AKS for a healthcare provider to pay distributors and independent sales agents marketing their products to prescribers based on the volume of sales.

83. By submitting claims for reimbursement of services that violated the AKS to federal healthcare programs other than FEHBP, the Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States.

84. Such acts were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

85. By reason of the Defendants' above conduct, they are liable to the United States for treble damages and penalties, in an amount to be determined at trial.

COUNT TWO
(Violation of 31 U.S.C. § 3729(a)(1)(B))

86. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

87. By submitting claims for reimbursement of services for prescriptions of Focused Pain Relief in states where FPR and Mead Square were not licensed, or would not have been licensed had they provided truthful information to the state pharmacy boards, or for claims that violated the AKS, the Defendants made, used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States.

88. Such acts were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

89. By reason of the Defendants' above conduct, they are liable to the United States for treble damages and penalties, in an amount to be determined at trial.

COUNT THREE
(Unjust Enrichment)

90. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

91. Through the acts set forth above, FPR and Mead Square have received payments from federal healthcare programs to which they were not entitled and therefore have been unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Defendants should not retain those payments, the amount of which are to be determined at trial.

COUNT FOUR
(Payment by Mistake of Fact)

92. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

93. The Government seeks relief against Defendants to recover monies paid under mistake of fact.

94. The Government made payments to FPR and Mead Square in connection with prescriptions of Focused Pain Relief for beneficiaries of federal healthcare programs based on a mistaken and erroneous understanding that the claims for these prescriptions were dispensed by pharmacies licensed in the states where the beneficiaries were located and were not tainted by illegal kickbacks.

95. Had the Government known of Defendants' actions, the federal healthcare programs would not have paid FPR and Mead Square for the prescriptions at issue.

96. By reason of the foregoing, the Government has sustained damages in an amount to be determined at trial.

WHEREFORE, the United States requests that judgment be entered in its favor and against the Defendants as follows:

(a) On Counts I and II, treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(A) 3729(a)(1)(B) or for each violation;

(b) On Counts III and IV, a judgment against Defendants for damages to the extent allowed by law;

(c) an award of costs pursuant to 31 U.S.C. § 3729(a)(3); and

(d) such further relief as is proper.

Dated: New York, New York
March 30, 2020

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

By: s/Jean-David Barnea
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