UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 15-62617-CIV-BLOOM

UNITED STATES OF AMERICA
ex rel. MARISELA CARMEN MEDRANO
and ADA LOPEZ,

Plaintiffs,

v.

DIABETIC CARE RX, LLC, d/b/a
PATIENT CARE AMERICA;
RIORDAN, LEWIS & HADEN, INC.;
PATRICK SMITH; and
MATTHEW SMITH,

Defendants.
_____/

THE UNITED STATES OF AMERICA'S
FIRST AMENDED COMPLAINT IN INTERVENTION

The United States of America (the "United States" or the "Government"), on behalf of the United States Department of Defense ("DOD"), brings this action against Defendants Diabetic Care Rx, LLC, d/b/a Patient Care America ("PCA"); Riordan, Lewis & Haden, Inc. ("RLH"); Patrick Smith; and Matthew Smith.

I. INTRODUCTION

1. This is a civil action brought by the United States against the Defendants under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and the common law, to recover treble damages sustained by, and civil penalties and restitution owed to, the United States based on Defendants' illegal scheme to knowingly present, and cause to be presented, false or fraudulent claims for compounded drugs to TRICARE, the federal health care program for active duty military personnel, retirees, and their families. As part of the scheme, Defendants paid kickbacks

to "marketers" to target military members and their families for prescriptions for compounded pain creams, scar creams, and vitamins, regardless of need. While these products were supposed to be compounded specifically for individual patients' needs, the formulations were in reality manipulated by the Defendants and marketers to ensure the highest possible reimbursement from TRICARE. The marketers paid telemedicine doctors who prescribed the creams and vitamins but never physically examined the patients. The marketers also colluded with the Defendants to pay many patients' copayments to induce them to accept the compounded drugs. The Defendants and marketers then split the profits, and the scheme generated millions of dollars for them in a matter of months.

2. As set forth below, as part of this scheme, from September 1, 2014 to April 29, 2015, Defendant PCA knowingly submitted claims to TRICARE for reimbursement for compounded drugs that were false or fraudulent because they were tainted by kickbacks to marketers and patients and did not arise from a valid patient-prescriber relationship. Defendant Matthew Smith knowingly caused the submission of false or fraudulent claims from September 1, 2014 to April 29, 2015; Defendants RLH and Patrick Smith knowingly caused the submission of false or fraudulent claims from January 1, 2015 to April 29, 2015.

II. PARTIES

3. Plaintiff the United States brings this action on behalf of the DOD, including DOD component the Defense Health Agency ("DHA"), which administers the TRICARE program.

4. Relators Marisela Medrano and Ada Lopez are former employees of Defendant PCA who allege that Defendants violated the False Claims Act by paying illegal kickbacks to marketing companies to secure prescriptions for compounded drugs reimbursed by TRICARE.

5. Defendant PCA is a pharmacy organized under the laws of the State of Florida, with its principal place of business in Pompano Beach, Florida, that received over $72 million in reimbursements from TRICARE for compounded drug claims from September 1, 2014 to April 29, 2015.

6. Defendant RLH is a private equity firm based in Los Angeles, California. RLH is the manager of a private equity fund, RLH Investors III, LP and RLH III – RJR MS, LP (collectively "Fund III"), which has owned a controlling stake in PCA since July 15, 2012. A related entity, Riordan, Lewis & Haden III, LLC, is the general partner of RLH Investors III, LP and RLH III – RJR MS, LP. At all relevant times, RLH managed and controlled PCA on behalf of the private equity fund through two RLH partners, Michel Glouchevitch and Kenneth Hubbs, who served as officers and/or directors of PCA and of two holding companies with an ownership interest in PCA.

7. Defendant Patrick Smith, who resides in Palm Beach Gardens, Florida, has been PCA's Chief Executive Officer since March 10, 2014.

8. Defendant Matthew Smith, who resides in Boca Raton, Florida, was PCA's Vice President for Operations and led PCA's topical compounding business from April 15, 2014 through April 29, 2015.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345 because this action is brought by the United States as a Plaintiff pursuant to the False Claims Act.

10. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) and because Defendants reside or transact business in the Southern District of Florida.

11. Venue is proper in the Southern District of Florida under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendants reside or transact business in this District.

IV. BACKGROUND

A. The False Claims Act And Anti-Kickback Statute

12. The FCA establishes liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), "knowingly 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), or "conspires to commit a violation of subparagraph (A) [or] (B)," *id.* § 3729(a)(1)(C). "Knowingly" is defined to include actual knowledge, reckless disregard, or deliberate indifference. *Id.* § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

13. The Anti-Kickback Statute ("AKS") arose out of congressional concern that inducements may corrupt patient and professional health care decision-making, impose higher costs on federal health care programs, and divert federal funds towards goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the federal health care programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] 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—

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, 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).

14. A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a)(1)(A)-(B). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

15. Specific intent is not required to establish a violation of the AKS. *See* 42 U.S.C. § 1320a-7b(h) ("With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

16. The AKS contains several exceptions in which the prohibitions against providing compensation in exchange for referrals or orders do not apply. The "bona fide employment" exception provides that "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services" will not violate the AKS. 42 U.S.C. § 1320a-7b(b)(3)(B). This type of compensation to bona fide employees is exempt from the statute's prohibitions because the control that employers exercise over bona fide employees reduces the potential for abuse. *See*

Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991).

17. As set forth in more detail below, Defendants knowingly and willfully paid remuneration to marketers to obtain referrals for compound drugs reimbursed by TRICARE. At no time did Defendants have a bona fide employment relationship with the marketers to whom they paid such remuneration.

18. As set forth in more detail below, Defendants knowingly and willfully offered and paid remuneration to patients to induce the patients to purchase drugs reimbursed by TRICARE by waiving or satisfying copayments that the patients were obligated to pay or by providing other remuneration.

19. By providing kickbacks to marketers and patients to induce prescriptions for compounded drugs reimbursed by TRICARE, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the TRICARE program.

20. As set forth in more detail below, Defendants knowingly and willfully submitted or caused to be submitted claims to TRICARE for prescriptions that were not supported by a valid patient-prescriber relationship.

21. As set forth in more detail below, Defendants made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim. Such false records or statements include PCA's Provider Agreement, discussed below, and the prescriptions that did not arise from a valid patient-prescriber relationship.

22. As set forth in more detail below, RLH and PCA conspired to violate the FCA by submitting or causing to be submitted false or fraudulent claims and by making, using, or causing to be made or used false statements and records.

B. The TRICARE Program

23. TRICARE (formerly known as CHAMPUS) is a federal health care program, as defined in the AKS, 42 U.S.C. § 1320a-7b, that is administered by DHA, a component of the DOD. TRICARE provides health care insurance for active duty military personnel, military retirees, and military dependents.

24. TRICARE contracts with Express Scripts, Incorporated ("ESI") to administer the prescription drug coverage of the TRICARE program, including the processing and payment of claims for reimbursement from TRICARE for compounded prescription drugs.

25. At all relevant times, TRICARE covered compounded drugs that are medically necessary and proven to be safe and effective. 32 C.F.R. § 199.4 (g)(15). Compounding is the practice in which a licensed pharmacist or physician combines, mixes, or alters the ingredients of a drug to create a medication tailored to the needs of an individual patient. A patient may need a compounded drug, for example, if she is allergic to an ingredient in a manufactured drug.

26. From at least September 1, 2014 to May 1, 2015, TRICARE reimbursed pharmacies for all the ingredients in a compounded drug. During this period, retail or mail-order pharmacies were paid lesser of (1) the pharmacy's Usual and Customary price for the compound drug or (2) the Average Wholesale Price of each ingredient in a compounded drug minus a negotiated discount.

27. On March 5, 2015, TRICARE publicly announced that beginning on May 1, 2015, it would screen "all ingredients in compound drug claims to ensure they are safe and effective and covered by TRICARE." The new screening process checked to ensure that the ingredients were lawfully marketed in the United States, were safe and effective, and were medically necessary. To the extent drugs were rejected by the screening process, a doctor could

request prior authorization for the compound. TRICARE paid far fewer claims for compounded drugs after implementing these changes on May 1, 2015.

28. At all relevant times, TRICARE beneficiaries were responsible for sharing the costs of compounded drug prescriptions filled by a retail or mail-order pharmacy by paying a copayment. 10 U.S.C. § 1074g(a)(6); TRICARE Reimbursement Manual, Chapter 2, Addendum B.

29. A pharmacy seeking reimbursement from TRICARE must comply with TRICARE's anti-fraud and abuse provisions. 32 C.F.R. § 199.9(a)(4). Fraudulent situations include commission and kickback arrangements. *Id.* § 199.9(c)(12). Abusive situations include the routine waiver of patient copayments. *Id.* § 199.9(b)(1).

30. Fraud or abuse by a pharmacy may result in the denial of the pharmacy's claims or the exclusion or suspension of the pharmacy from participation in the TRICARE program. 32 C.F.R. § 199.9(b), (f).

31. To receive reimbursement from TRICARE for compounded drugs, a pharmacy must enter into a Provider Agreement with ESI, TRICARE's pharmacy benefits manager. A Provider Agreement is essential to TRICARE claims submission. Having a valid Provider Agreement was required in order to submit claims for compounded drug reimbursement to TRICARE. PCA submitted such a Provider Agreement to ESI and used it to obtain reimbursement from TRICARE for compounded drugs from September 1, 2014, to April 29, 2015.

32. TRICARE regulations specify that "[a]ll fraud, abuse, and conflict of interest requirements [in section 199.9] are applicable to the TRICARE pharmacy benefits program." 32

C.F.R. § 199.21(p). TRICARE's contract with ESI also incorporates the provisions of 32 C.F.R. § 199.

33. On August 28, 2012, PCA executed a Provider Agreement with ESI in which PCA agreed to:

a. "be bound by and comply with the provisions of this Agreement and all applicable laws, rules and regulations including, but not limited to, fraud waste and abuse laws …."

b. "not submit a claim to ESI until it has preliminarily determined … that the prescription presented is valid and issued in accordance with applicable laws, rules and regulations."

c. "collect from [patients] … the applicable [c]opayment" and not "waive[] or discount[]" copayments unless directed by ESI.

34. In the Provider Agreement between ESI and PCA, ESI expressly reserved the right to reverse any claim that PCA submitted for a prescription when PCA "failed to … verify that the prescription was issued in accordance with applicable laws, rules and regulations."

35. In addition, PCA agreed in its Provider Agreement with ESI to comply with ESI's Provider Manual.

36. The ESI Provider Manuals in effect during the period from September 1, 2014 to April 29, 2015 required PCA to "ensure that the correct Copayment is charged" to the patient and "is not changed or waived." The Manuals further warned that if ESI "becomes aware of any Copayment or cost-sharing discounts offered" by PCA, then PCA "may be subject to immediate termination" from ESI's provider network.

37. The ESI Provider Manuals in effect during the period from September 1, 2014 to April 29, 2015 also required PCA to be aware of and comply with all state and federal law, "including anti-kickback statutes and self-referral statutes." The Manuals warned that "[f]ailure to demonstrate compliance with these laws may result in immediate termination by [ESI]."

38. In addition, TRICARE covers pharmacy services but requires that "pharmacies [] meet the applicable requirements of state law in the state in which the pharmacy is located." 32 C.F.R. § 199.6(d)(3); *see also* TRICARE Policy Manual 6010.57-M, Ch. 8, Sec. 9.1 (Feb. 1, 2008 and April 1, 2015).

39. Under Florida law, a pharmacy may lose its license to dispense drugs if it dispenses a drug based on a prescription that a pharmacist knows or has reason to believe is not based on a valid patient-prescriber relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which the drug is prescribed. Fla. Stat. § 465.023(1)(h).

40. As set forth below, by billing TRICARE for compounded drugs that were induced by kickbacks to marketers and patients and prescribed by practitioners who Defendants knew, or should have known, did not have a valid patient-prescriber relationship with the patients, Defendants presented, or caused to be presented, false or fraudulent claims to the TRICARE program, and Defendants knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the TRICARE program.

41. Each claim that PCA submitted to TRICARE for reimbursement conveyed, among other things, information about the patient, the prescriber, the pharmacy, the ingredients in the prescribed drug, the price of the ingredients, and the date the prescription was filled. By submitting this information on the claim, PCA implicitly represented that the compounded drug

and its ingredients were medically necessary and appropriate for the patient based on a sufficient clinical evaluation of the patient by the prescriber, and that the decision to prescribe or dispense the compounded drug, and its particular ingredients, was not tainted by inducements prohibited by the AKS. By failing to disclose that the referral of the prescription was induced by an illegal kickback, or that the prescriber wrote the prescription without a sufficient clinical evaluation of the patient, these specific representations on the claim were false and misleading.

42. PCA violated the express representations it made in its Provider Agreement to abide by fraud and abuse laws by virtue of the conduct alleged below.

43. PCA knowingly used the expressly false representations in its Provider Agreement to submit and obtain reimbursement for compounded drugs from TRICARE from September 1, 2014, to April 29, 2015. TRICARE relied on the representations made by PCA at the time it paid PCA's claims, and if TRICARE had known that representations in PCA's Provider Agreement were false, TRICARE would not have paid these claims.

44. For these reasons, PCA's Provider Agreement constituted expressly false statements and/or an expressly false record used to get false claims paid.

45. In order to obtain reimbursement from TRICARE for dispensing compounded drugs, PCA submitted electronic data claims to ESI. After receiving a claim, ESI adjudicated the claim on behalf of DHA. If the claim was successfully adjudicated, then ESI sent the pharmacy authorization to dispense the drug. ESI also sent DHA a data record of the claim, and, after a holding period, ESI paid the pharmacy on the claim from a government-established and government-funded account created for the purpose of paying TRICARE reimbursement claims.

46. Such reimbursement claims are therefore claims within the meaning of 31 U.S.C. § 3729(B)(2).

V. FACTS

A. RLH Acquired DCRX And Planned To Sell It For A Profit In Five Years

47. The pharmacy now known as PCA was founded in 2006 as Diabetic Care Rx LLC ("DCRX"). DCRX was a sterile compounding pharmacy that provided intravenous nutritional therapy to End Stage Renal Disease patients receiving dialysis.

48. In July 2012, RLH made a controlling investment in DCRX through the private equity fund, Fund III. In its capacity as the manager of Fund III, RLH controlled and directed the conduct of DCRX on behalf of investors in the fund. RLH partners Michel Glouchevitch and Kenneth Hubbs became officers of DCRX, which was managed by DCRX Acquisition Corporation, of which Glouchevitch and Hubbs served as both officers and board members. Through Fund III's controlling stake in DCRX, RLH controlled a majority of the seats on DCRX's board of directors.

49. At the time that DCRX was acquired, RLH managed other health care companies, including Avella, a specialty pharmacy similar to DCRX.

50. At the time DCRX was acquired, RLH planned to increase DCRX's value and sell it for a profit in five years. DCRX's primary source of revenue when RLH acquired DCRX was Medicare, a federal health care program for qualified individuals aged 65 and older, younger people with qualifying disabilities, and people with End Stage Renal Disease regardless of age. Shortly after DCRX was acquired, Medicare reimbursement rates dropped for the nutritional therapy that DCRX provided to End Stage Renal Disease patients, and DCRX's revenue correspondingly dropped. Restoring DCRX's profitability became RLH's primary objective.

B. RLH Directed DCRX's Entry Into Topical Compounding Because Of Its Extraordinary Profitability

51. In November 2013, RLH initiated DCRX's entry into the business of non-sterile compounding of topical creams for "pain management" to capitalize on "the extraordinarily high profitability of this therapy," which RLH anticipated could result in a "quick and dramatic payback" on its investment in DCRX.

52. RLH partners Glouchevitch and Hubbs were the DCRX board members who led the pain management initiative. By January 2014, the board had determined that insurance reimbursement ranged from $1,000.00 to $8,000.00 per prescription of compounded pain cream, and the gross profit margin was approximately 90 percent.

53. The board, including RLH partners Glouchevitch and Hubbs, contemplated from the outset that the pharmacy would bill the federal government for compounded creams. It directed further research into Medicare coverage of pain creams for the pharmacy's existing customer base of End Stage Renal Disease patients.

54. RLH also recognized that the unbelievably high profit margins for topical compounding likely would not last. RLH's goal, therefore, was to use the topical compounding business to generate a "very fast payback on [its] investment," or in the words of RLH partner Glouchevitch, to "make hay while the sun shines."

55. While doing so, RLH recognized that "overcharging for product" in its "pain management business" risked "cross[ing] the line from an ethics standpoint."

C. Patrick Smith And Matthew Smith Were Hired To Drive Referrals And Profits

56. RLH sought out a new CEO for DCRX to work closely with RLH to launch the new topical compounding business and increase the company's value by the time that RLH planned to sell the company.

57. In February 2014, RLH partner Glouchevitch recommended hiring Patrick Smith as CEO. Patrick Smith had previously served as CEO of two health care companies, Critical Care America, which provided home infusion services, and Curaxis, a drug development company.

58. Glouchevitch recommended Patrick Smith for the CEO position despite being warned by a talent consultant, which RLH retained to evaluate Mr. Smith's likelihood of success as CEO, that although Patrick Smith had "the skills and experiences needed to successfully drive significant growth at DCRX," he would "require more careful management than [RLH] may wish to provide."

59. Based on Glouchevitch's recommendation, the board agreed to hire Patrick Smith as CEO in March 2014.

60. RLH directed and oversaw Patrick Smith by, among other things, obtaining his agreement to get RLH's approval for key decisions affecting the company. In an April 18, 2014 letter to Patrick Smith, sent on RLH letterhead and signed on behalf of RLH by Glouchevitch, RLH noted that "the best results for management and RLH are achieved when there is a true spirit of partnership between us." The letter explained that "[a] strong partnership helps us (i) fulfill our fiduciary duties to our investors who have entrusted us with their capital, (ii) avoid surprises that could strain the relationship between your team and RLH, and (iii) more effectively advise you on important decisions." Accordingly, RLH required "Joint Decision

Making" with Patrick Smith. RLH explained: "A key role for RLH in our collaboration is to help you make the best decisions for the company by offering a fresh outside perspective on matters which could have a material impact on the value of the business. . . . The most effective way for us to provide this valuable perspective is by our participation in important decisions starting at an early stage in the consideration process. You have our commitment that we will be responsive, open minded, and flexible as we work with you to make decisions that are consistently in the best interest of DCRX." For example, RLH expected Patrick Smith to "consult with RLH" before (1) entering into written employment agreements, (2) hiring, terminating, or promoting any employee whose total annual compensation is in excess of $120,000, (3) entering into any type of contract that obligated the company to make annual payments over $50,000.00 or total payments over $150,000.00, or (4) promising "to issue any new stock, options, or other equity-type securities to any employee." In addition, the letter required that the "annual budget [be] finalized and approved by the Board by the end of the prior calendar year."

61. Based on Glouchevitch's recommendation, the board also agreed to offer Patrick Smith a compensation plan that incentivized him to significantly grow the value of the business. In addition to an annual salary and bonuses, once the company became profitable, Mr. Smith was offered stock options that would allow him to receive millions of dollars if the pharmacy's value reached a certain benchmark by the time RLH sold the pharmacy.

62. As CEO of DCRX, Patrick Smith agreed with RLH that the topical compounding business was an opportunity DCRX should pursue, and he took the lead for PCA in developing it.

63. In April 2014, Patrick Smith hired Matthew Smith, a licensed pharmacist, to lead DCRX's new topical compounding business. In explaining his choice of Matthew Smith to the board, Patrick Smith emphasized Matthew Smith's "networks" in the area of topical compounding. Patrick Smith's expectation that Matthew Smith's connections in topical compounding would "generate immediate referrals as soon as we are operational" was a significant factor influencing Patrick Smith's decision to hire Matthew Smith to lead DCRX's topical compounding business.

64. Pursuant to the agreement between RLH and PCA, Matthew Smith launched the topical compounding business in the Fall of 2014, generating immediate and significant revenues.

D. PCA Paid Kickbacks To Marketers For Referring TRICARE Patients Or Arranging For Or Recommending That TRICARE Patients Order Prescriptions From The Pharmacy

65. By May 2014, DCRX had decided to use "independent contractors," rather than employed sales staff, to generate prescriptions for topical compounds. RLH knew of and agreed to this plan.

66. Beginning in July 2014, DCRX entered into independent contractor agreements with the three marketing companies who would become the source of over 95 percent of PCA's topical compounding revenue.

67. In July 2014, DCRX entered into a "Business Associate Agreement" with MDataRx, LLC, a marketing company owned and operated by Erik Santos.

68. In July 2014, DCRX entered into a "Marketing Services Agreement" with TeleMedTech, a marketing company owned and operated by Jonah Miller a/k/a Steve Miller ("Steve Miller").

69. In September 2014, DCRX entered into a "Consulting Agreement" with MG Ten, a marketing company owned and operated by Monty Grow.

70. The only services that MDataRx, TeleMedTech, and MG Ten agreed to perform for PCA under the contracts were referring patients to the pharmacy for compounded drug prescriptions, or arranging for or recommending patients' ordering of compounded drugs from the pharmacy.

71. For example, the "duties" that MDataRx agreed to fulfill pursuant to its "Business Associate Agreement" with PCA were to "solicit orders for" and "market" the pharmacy's products.

72. Similarly, the services that TeleMedTech agreed to provide pursuant to its "Marketing Services Agreement" with PCA were "completed prescriptions on patients[']behalf," or patient "leads," which were defined as "specific data fields collected by [TeleMedTech] of Individuals interested in [the pharmacy's] products."

73. The only compensation PCA agreed to pay MDataRx, TeleMedTech, and MG Ten under the contracts were commissions equal to 50 percent of the pharmacy's profit from prescriptions the marketer sent to the pharmacy.

74. For example, DCRX's "Consulting Agreement" with MG Ten required PCA to "pay [MG Ten] a fee equal to fifty percent of the cash amounts actually collected by [the pharmacy], net of [the pharmacy's] associated cost of goods sold, from referrals to [the pharmacy] (1) by referral sources that [MG Ten] develops pursuant to its services and (2) that relate to prescriptions for topical compounds for pain, scar and wound treatments or other treatments."

75. For tax purposes, the marketers were classified as 1099 contractors, not W-2 employees. There was no employment relationship between PCA and the marketing companies or their employees.

76. For example, the lack of employment relationship was explicit in TeleMedTech's "Marketing Services Agreement" with DCRX, which provided that "Marketer is not an employee of the [PCA] for any purpose whatsoever, but is an independent contractor[;] The [pharmacy] is interested only in the results obtained by the Marketer, that shall have sole control of the manner and means of performing under this Agreement."

77. MDataRx's "Business Associate Agreement" with DCRX contained similar language: "Business Associate shall be deemed an independent contractor, and nothing herein shall be construed to establish between Business Associate and [PCA] the relationship o[f] employer-employee, partnership or joint venture."

78. MG Ten's "Consulting Agreement" with DCRX also did not create an employment relationship between the parties. The agreement only obligated MG Ten to provide PCA "business development services" for "topical compounds," and only required the pharmacy to pay MG Ten a "fee" equal to 50 percent of the pharmacy's profit on each prescription for "topical compounds" generated by MG Ten.

79. RLH, PCA, Patrick Smith, and Matthew Smith knew that Erik Santos, Steve Miller, and Monty Grow were not employees of PCA.

80. Matthew Smith negotiated PCA's contracts with the companies owned by Erik Santos, Steve Miller, and Monty Grow.

81. In the summer of 2014, Matthew Smith forwarded draft contracts that he received from the marketers to David Corcoran, an attorney who served as a part-time general counsel for

PCA. Around the same time and in connection with PCA's entry into the topical compounding business, Mr. Corcoran advised Matthew Smith and Patrick Smith that (1) they should not pay doctors; (2) their independent marketers should not pay third-party referral sources; and (3) the company should not be billing government health care programs. He also discussed with them the AKS.

82. As early as May 29, 2014, Matthew Smith informed the Board of Directors in a meeting attended by Hubbs and Glouchevitch that the sales and marketing for non-sterile compounding was being conducted by independent contractors.

83. Beginning in September 2014, PCA regularly received prescriptions for TRICARE patients by email or fax from the marketers, rather than from the patients or prescribers.

84. By at least December 2014, Patrick Smith and RLH knew that the majority of PCA's topical compounding revenue was coming from TRICARE and being generated by MDataRx, TeleMedTech, and MG Ten, rather than the pharmacy's employed sales staff.

85. On December 15, 2014, Patrick Smith sent Hubbs and Glouchevitch a 2015 budget. That budget projected that in 2015 PCA would have net revenue of $51,285,000 in the non-sterile compounding business line, of which $24,075,178 would be paid in commissions to marketers.

86. On December 16, 2014, Patrick Smith informed RLH that TRICARE was the source of $2.44 million in topical compounding revenue from October 1 through December 12, 2014, which was half of PCA's topical compounding revenue during that period. In the same communication, Patrick Smith conveyed to RLH that marketers MG Ten, TeleMedTech, and MDataRx generated approximately 75 percent of PCA's topical compounding revenue.

87. On January 15, 2015, a PCA employee sent Hubbs and Glouchevitch a revised 2015 budget. That budget projected that in 2015 PCA would have net revenue of $70,848,000 in the non-sterile compounding business line, of which $33,778,481 would be paid in commissions to marketers.

88. On January 27, 2015, RLH partners Glouchevitch and Hubbs were informed by Matthew Smith at a board meeting led by Patrick Smith that TRICARE was the source of $11.7 million in topical compounding revenue, which was over 75 percent of PCA's total compounding revenue during that period. Matthew Smith further informed the meeting attendees that over $5.6 million of PCA's topical compounding revenue had been referred by MG Ten, and over $4.8 million of PCA's topical compounding revenue had been referred by MDataRx.

89. During the January 27, 2015, board meeting, Patrick Smith also reported that the company had changed its operating name to Patient Care America.

90. On February 4, 2015, Hubbs circulated a revised 2015 budget to Glouchevitch, Patrick Smith, and others. That budget projected that in 2015 PCA would have net revenue of $159,181,010 in the non-sterile compounding business line, of which $75,893,360 would be paid in commissions to marketers.

91. On April 28, 2015, RLH partners Glouchevitch and Hubbs were informed by PCA's CFO at a board meeting attended by Patrick Smith and Matthew Smith that the percentage of topical compounding revenue from TRICARE had grown from approximately 75 percent at the beginning of 2015 to over 98 percent by March 2015. At the same meeting, Matthew Smith reported that the company had received over $69 million in total topical

compounding revenue in 2015 and that over $64 million of that revenue, or 90 percent, had been referred by MG Ten, TeleMedTech, and MData Rx.

92. In accordance with PCA's contracts with the marketers, PCA paid the marketers a percentage of the profit on each prescription that the marketer sent to the pharmacy.

93. From November 2014 through April 2015, PCA paid by wire transfer nearly $7.5 million to MDataRx.

Date	Payee	Amount
11/7/2014	MDATA Rx	**$257,276.92**
11/21/2014	MDATA Rx	**$115,952.20**
12/9/2014	MDATA Rx	**$642,877.35**
12/19/2014	MDATA Rx	**$348,308.37**
1/2/2015	MDATA Rx	**$865,249.70**
1/16/2015	MDATA Rx	**$259,643.21**
1/30/2015	MDATA Rx	**$928,955.80**
2/13/2015	MDATA Rx	**$482,171.30**
2/27/2015	MDATA Rx	**$457,099.86**
3/13/2015	MDATA Rx	**$668,236.33**
3/30/3015	MDATA Rx	**$517,958.44**
4/10/2015	MDATA Rx	**$981,516.44**
4/24/2015	MDATA Rx	**$963,117.34**
	TOTAL	**$7,488,363.26**

94. From November 2014 through April 2015, PCA paid by wire transfer over $6.7 million to TeleMedTech.

Date	Payee	Amount
11/7/2014	TeleMedTech	**$8,751.69**
12/18/2014	TeleMedTech	**$18,108.13**

1/2/2015	TeleMedTech	**$26,219.14**
1/16/2015	TeleMedTech	**$15,852.30**
1/30/2015	TeleMedTech	**$179,757.90**
2/13/2015	TeleMedTech	**$314,333.10**
2/27/2015	TeleMedTech	**$583,504.04**
3/13/2015	TeleMedTech	**$1,048,443.54**
3/27/2015	TeleMedTech	**$1,217,811.10**
4/10/2015	TeleMedTech	**$1,544,944.55**
4/27/2015	TeleMedTech	**$1,809,665.34**
	TOTAL	**$6,767,390.83**

95. From November 2014 through April 2015, PCA paid by wire transfer over $19.5 million to MG Ten.

Date	**Payee**	**Amount**
11/7/2014	MG Ten	**$85,945.75**
11/12/2014	MG Ten	**$5,000.00**
11/19/2014	MG Ten	**$20,000.00**
11/21/2014	MG Ten	**$74,662.59**
12/9/2014	MG Ten	**$210,762.94**
12/18/2014	MG Ten	**$288,290.50**
1/2/2015	MG Ten	**$732,974.48**
1/20/2015	MG Ten	**$450,000.00**
1/20/2015	MG Ten	**$436,489.95**
1/30/2015	MG Ten	**$17,500.00**
1/30/2015	MG Ten	**$1,206,816.80**
2/13/2015	MG Ten	**$1,964,740.80**
2/27/2015	MG Ten	**$2,322,450.90**
3/13/2015	MG Ten	**$3,644,893.60**

3/27/2015	MG Ten	**$1,630,902.80**
3/31/2015	MG Ten	**$125,000.00**
4/10/2015	MG Ten	**$62,500.00**
4/10/2015	MG Ten	**$4,425,543.80**
4/27/2015	MG Ten	**$1,832,268.40**
	TOTAL	**$19,536,743.31**

96. Patrick Smith and Matthew Smith tracked payments to PCA's outside marketers and ensured that the relevant commissions were paid on all patients referred by the marketers and in accordance with the contracts with those marketers.

97. Each month, Patrick Smith sent the prior month's financial statements to PCA's board members, including Glouchevitch and Hubbs. Among other things, each statement reported the month's topical compounding revenue and "commission" payments to the marketers.

	Compounding Sales Revenue	**Compounding Commissions**
09/14	$237,622.20	$98,996.67
10/14	$1,104,864.88	$533,562.73
11/14	$2,401,147.68	$1,104,756.60
12/14	$5,037,150.76	$2,592,819.32
01/15	$9,259,522.75	$4,962,506.61
02/15	$15,872,586.88	$7,551,357.56
03/15	$23,456,718.89	$11,272,857.68
04/15	$28,164,207.33	$13,907,594.42
TOTAL	**$85,533,821.37**	**$42,024,451.59**

98. The notes to the financial statements characterized the commissions as "an agreed cost based on compounding sales."

99. RLH periodically funded commission payments to the marketers that were due before PCA received reimbursement for the prescriptions, even after RLH knew that the marketers were earning commissions on prescriptions reimbursed by TRICARE. RLH knew that the money it was providing to PCA was to be used to pay commissions to the marketers.

100. On December 24, 2014, Patrick Smith asked RLH for cash to fund commissions as "sales are still ahead of collections."

101. Again on January 15, 2015, Patrick Smith wrote to Glouchevitch and Hubbs that "we continue to monitor cash very closely and it continues to be tight." That same day, Patrick Smith wrote to Glouchevitch and Hubbs to renew his request for cash: "I am anxiously awaiting some payments, but I am short for tomorrows [sic] commission payments." In response, Glouchevitch asked Patrick Smith if there is "anyway to stretch vendors?" Patrick Smith responded, "We can stretch vendors, but It's the consultant marketing groups that are very demanding."

102. On January 27, 2015, there was a board meeting attended by Patrick Smith, Glouchevitch, and Hubbs among others. PCA's cash flow was one topic addressed during the board meeting. During the January 27, 2015 board meeting, the board voted to provide Matthew Smith with an incentive stock option package of 2,000 shares of PCA stock worth $100.00 per share based on his work on the non-sterile compounding line.

103. On January 28, 2015, Glouchevitch wrote to Hubbs and others concerning the cash flow problem caused by the marketer commissions. He noted that "the company can grow sequentially at about 18% per month and the company will not require cash. . . . The numbers are insane. With a line you can grow faster than what I'm projecting."

104. RLH wired PCA $2 million on January 29, 2015 pursuant to a promissory note PCA signed with Fund III.

105. The only work the marketers in fact performed for the Defendants in exchange for the payments was referring patients to PCA for compounded drug prescriptions or arranging for or recommending patients' ordering of compounded drugs from the pharmacy.

106. Consistent with their status as independent contractors, the marketers were not given specific work assignments by PCA. The pharmacy did not control how the marketers generated the prescriptions that the marketers sent to the pharmacy.

107. Marketers targeted TRICARE patients and persuaded some to become marketers themselves by referring other TRICARE patients they knew. After securing a patient's consent to accepting pain creams, scar creams, and/or wellness vitamins, the marketers sent the patient's information to a telemedicine doctor who the marketers were paying per "consultation." The telemedicine doctors never saw the patients or physically examined them. Sometimes, the telemedicine doctors would not speak to the patients at all.

108. Over half of the claims for which PCA was paid by TRICARE in the period from September 1, 2014 to April 29, 2015 were prescribed by only five providers. One of these providers, Dr. Paul Matthew Bolger, pleaded guilty to false statements relating to health care matters and misbranding on August 22, 2017. Dr. Bolger admitted that he signed prescriptions for compounded drugs that were then faxed to several pharmacies, including PCA, when he had not spoken to, conducted a physical evaluation of, or reviewed medical records for the patient. He also admitted to falsely attesting, when signing the prescriptions, that he had reviewed the patients' medical records and determined the prescriptions were medically necessary, when in fact, he had not established a doctor-patient relationship with the patients and had not made an

independent, professional judgment that the drugs were medically necessary for the patients. He further admitted that PCA billed and received payment from TRICARE for these prescriptions containing materially false statements.

109. In the period from September 1, 2014 to April 29, 2015, over 80 percent of PCA's claims for TRICARE reimbursement were for patients who resided outside of Florida, and the majority of PCA's top prescribers were located outside of Florida as well.

110. PCA rarely had contact with the individuals who prescribed the drugs for the patients. The prescribers were considered clients of the marketers. As Matthew Smith explained in a November 4, 2014 email, "[m]ost of our referral sources like to handle [communications with the prescribers] on their own so they can manage the client."

111. For example, MDataRx's control over the relationship between the patient, prescriber, and pharmacy was explicit in MDataRX's "Business Associate" agreement with PCA, which specified that:

a. "[PCA] shall not have the power to oversee and supervise [MDataRx] with respect to the means and manner in which [MDataRx] performs functions hereunder."

b. "MDataRx will handle all customer service for the relationship of the physicians, patients and pharmacy related to the MDataRx relationships."

112. TeleMedTech's "Marketing Services Agreement" with PCA similarly provided that the pharmacy "is interested only in the results obtained by the Marketer, that shall have sole control over the manner and means of performing under this Agreement."

113. PCA's payments to the marketers were intended to induce the marketers to send prescriptions to PCA. PCA did not control the pharmacies to which the marketers sent their

prescriptions. The marketers selected the pharmacy to use to fill the prescriptions. PCA knew that the marketers were at times sending their prescriptions to other pharmacies.

114. TeleMedTech's agreement with PCA expressly provided that "[t]he Marketer may represent other Clients in the Compounding pharmacy business."

115. Erik Santos of MDataRx frequently indicated to PCA that TRICARE prescriptions would be sent to another pharmacy if PCA could not process the prescriptions more quickly or profitability.

116. For example, on October 20, 2014, Erik Santos complained to Matthew Smith about a two-week delay in processing the TRICARE prescriptions that Mr. Santos had sent to PCA to be filled and conveyed that if PCA could not streamline its processing of TRICARE prescriptions "my guys will want to transfer to another pharmacy."

117. On October 29, 2014, Erik Santos informed Matthew Smith that another pharmacy was receiving at least 30 percent more TRICARE reimbursement for the same prescriptions and asked Matthew Smith to determine how to increase the TRICARE reimbursement for the prescriptions so that Mr. Santos could continue sending the business to PCA.

E. PCA Paid Patients' Copayments

118. PCA and TeleMedTech routinely split the cost of the copayments owed by patients referred to PCA by TeleMedTech, without any verification of the patients' financial need, and then disguised the payments as coming from a sham charitable organization, which was affiliated with TeleMedTech.

119. This scheme, which was directed by Matthew Smith and Steve Miller, the owner and operator of TeleMedTech, provided remuneration to patients by paying or waiving the

patient's copayment. The purpose of paying or waiving copayments was to induce patients to purchase medication by eliminating any financial barrier to their purchase of the drugs.

120. In discussing the scheme with Matthew Smith in a July 17, 2014 email, Steve Miller wrote, "[s]ometimes, as you know, that $40 copay stops people from ordering a $6000 medication, of which $5960 is free … lol," to which Matthew Smith responded, "Yes, I agree. I have been experiencing many 'no-go's' secondary to not wanting to pay a $20-$75 copay."

121. On August 4, 2014, Steve Miller confirmed with Matthew Smith that TeleMedTech was willing to fund the copayments for all patients referred by TeleMedTech to PCA, because TeleMedTech "will not lose a patient over a copay."

122. The "charity" that PCA and TeleMedTech used to further this scheme was called PFARN. It performed no function other than serving as a conduit for TeleMedTech and PCA to fund the copayments for patients referred by TeleMedTech.

123. As Steve Miller explained in an August 21, 2014, email to Matthew Smith, "[PFARN] will be sending 100% of the payment to PCA that is due for each client on behalf of each client so the pharmacy can ACT complaint [*sic*] – but since they only receive 50% of the profit [on the prescription], they only will pay 50% of the expense – the pharmacy covers the other 50% from their profit (thus equaling 100%) – this keeps things even and fair."

124. In furtherance of the scheme, Patrick Smith and Matthew Smith signed checks from PCA to PFARN for 50 percent of the cost of the copayment owed by the patients referred to PCA by TeleMedTech each month.

125. For example, Patrick Smith signed a check from PCA to PFARN dated February 6, 2015. The face of the check made clear that PFARN was associated with TeleMedTech because the memo line of the check listed both PFARN and TeleMedTech along with

TeleMedTech's address. The memo line also clearly stated that the payment was for "December 2014 Co-pay." The amount of the check – $3,448.09 – demonstrated that the payment was for numerous patients' copayments, not special cases of financial need.

126. Pursuant to the PFARN scheme, PCA routinely paid 50 percent of the cost of the copayments for patients referred by TeleMedTech. The routine nature of the payments was evident on the face of a check signed by Patrick Smith, dated February 23, 2015. The memo line stated "January 2015 Co-pay 50%" and the amount of the check – $5,518.19 – confirmed that significant numbers of patients' copayments were being paid by PCA and PFARN/TeleMedTech pursuant to the scheme.

127. After PFARN received PCA's check for 50 percent of the copayment amount for TeleMedTech patients, PFARN then sent PCA a cashier's check, generated from a bank or 7-Eleven convenience store, for each patient for the full copayment amount for each patient.

128. On March 11, 2015, Steve Miller apologized to Matthew Smith and pharmacy staff member Alisa Catoggio for delay sending PCA the cashier's checks, explaining it was "an epic effort" by PFARN staff to obtain them. He further relayed that because "most places have a CUMULATIVE $2000 limit," PFARN staff had to visit "5 separate stores to get enough cashiers checks while walking around with 10k in PFARNS staff's pocket." He concluded by stating that the next set of cashier's checks would come next week, "as it's another 6 store[s], $11k, 3 day process. But hey I can[']t complain :)"

129. PCA, Matthew Smith, and Patrick Smith knew that PFARN and TeleMedTech were inseparable. Steve Miller told Matthew Smith that PFARN and TeleMedTech had a "common parent company." At Steve Miller's request, PCA mailed its checks to PFARN to TeleMedTech's address.

130. There was no verification of financial need of the patients whose copayments were funded through this scheme.

131. When pharmacy staff questioned TeleMedTech's payment of copayments for TRICARE patients, Matthew Smith responded that PFARN was a "verified legit not for profit entity," and that TRICARE copayment assistance from PFARN was not prohibited.

132. From the outset, Matthew Smith knew that PFARN was not a legitimate copayment assistance charity. He knew it was nothing more than a front for ensuring that neither PCA nor TeleMedTech would "lose a patient" over a copayment.

133. According to PCA's own records, pursuant to the PFARN scheme, copayments were not collected from patients for 3,477 prescriptions for which TRICARE paid over $16 million.

134. PCA colluded with other marketers as well to pay kickbacks to patients by covering their copayments without regard to the patients' financial need and to induce them to accept compounded drugs reimbursed by TRICARE.

F. Prescriptions Were Not Based On Valid Patient Consent Or Patient-Prescriber Relationship

135. PCA and the marketing companies, not the prescribing doctors, designed the compounds to maximize the profit on each prescription.

136. In August 2014, pharmacy staff were told that if the "spread," or the difference between the reimbursement amount and the ingredient cost, was less than 50 percent, staff must discuss the prescription with Matthew Smith before dispensing the prescription and submitting a claim for reimbursement.

137. In response to marketers' requests, PCA staff submitted "test claims" to TRICARE to determine the reimbursement amount for prescriptions that the marketers were considering sending to the pharmacy.

138. For example, on January 2, 2015, Matthew Smith asked pharmacy staff whether they had submitted test claims for three formulas as requested by Erik Santos. Alisa Catoggio responded that they determined one of the ingredients was not profitable and were evaluating alternatives that would result in higher reimbursement.

139. Matthew Smith praised pharmacy staff when they adjusted formulas to maximize reimbursement. For example, on December 29, 2014, Matthew Smith praised Alisa Catoggio for "reviewing all the Tricare claims to assure maximum reimbursement," adjusting claims when a "lower reimbursement" ingredient was used, and changing PCA's billing system to only bill the higher-reimbursing ingredient.

140. When PCA and the marketing companies determined the most profitable compounds, the marketing companies then arranged for those compounds to be ordered for hundreds of patients. For example, in the period from September 1, 2014 through April 29, 2015, the compound for which the highest total amount was paid by TRICARE was a scar cream that was claimed for 454 patients and reimbursed an average of $16,880.00 per claim. This compound was prescribed by 43 different providers.

141. As a result of PCA's efforts to maximize profit, the average reimbursement amount per prescription increased over time.

142. On October 28, 2014, RLH partners Glouchevitch and Hubbs were informed by Matthew Smith at a board meeting attended by Patrick Smith that the average reimbursement per

compounded drug prescription had increased from $803 in September 2014 to $1,672 in October 2014.

143. At the board meeting held on January 27, 2015, Matthew Smith informed the attendees, including Glouchevitch, Hubbs, and Patrick Smith, that average reimbursement per compounded drug prescription had further increased from $1,672 in October 2014, to $2,972 in November 2014, to $4,371 in December 2014, to $6,695 in January 2015.

144. PCA and the marketing companies' collusion in arranging for TRICARE patients to order the prescriptions that resulted in the most profit for the pharmacy and marketers improperly influenced the selection of ingredients in compound formulas.

145. From September 2014 through April 2015, patients regularly called PCA complaining that they had not ordered the cream or spoken to the doctor who purportedly prescribed it.

146. For example, on September 26, 2014, Matthew Smith was informed by PCA staff of a patient who complained that she did not know the doctor who purportedly prescribed the medication she received from PCA. The patient told PCA that she had never seen or heard from the doctor.

147. On December 26, 2014, Matthew Smith was informed by PCA staff that another patient had complained that she had not authorized the pharmacy to send her any prescriptions.

148. On February 20, 2015, Patrick Smith was informed by Matthew Smith that another patient had complained that he had not authorized the prescriptions and that his primary doctor had not approved them and had advised him not to use them.

149. The complaints also revealed that the marketers were at times misleading or harassing patients into agreeing to the prescriptions.

150. For example, on February 27, 2015, a "[c]ustomer called in extremely upset[,] [s]tat[ing] she does not have any pain, does not know who [the] doctor is, and does not want these product[s]." The customer further conveyed that "she did not ever talk to a doctor[;] she talked to a salesman who called her and he was very insistent [that] she try the products even after she insisted she did not have any pain whatsoever."

151. Marketers, in fact, pushed creams on TRICARE patients who did not need them, in order to increase the number of prescription referrals to PCA. One marketer, Ginger Lay, induced patients to accept the prescriptions by offering them cash for filling out a "survey" of their experience using the creams. The survey was intended as a way to pay patients kickbacks for accepting prescriptions they did not need. Lay, who worked for Monty Grow, pled guilty on January 5, 2018 to conspiracy to commit health care fraud in connection with this scheme. Some patients were paid directly for their own prescriptions. Many patients were paid for prescriptions for their spouse, children, or other family members. These kickbacks to TRICARE patients demonstrates that profit, not medical need, drove prescriptions.

152. Even though the complaints revealed that the prescriptions were being generated by the marketers without valid patient consent or patient-prescriber relationship, PCA continued to bill for the prescriptions referred by the marketers.

153. Matthew Smith instructed staff not to reverse any claims without discussing it with him first, and at times instructed staff not to reverse claims in response to patient complaints. Matthew Smith also instructed staff to credit all charges to a patient if necessary to prevent the patient from complaining to the patient's health insurance provider.

G. Defendants Were Aware Of The Prohibitions Of The AKS

154. Having been in the health care industry for many years serving End-Stage Renal Disease patients, PCA was familiar with and trained its employees on laws and regulations governing billing to federal health care programs, including the AKS.

155. As an investor in health care companies, RLH knew when it acquired PCA in July 2012, that health care providers that bill federal health care programs are subject to laws and regulations designed to prevent fraud, including the AKS.

156. For example, the July 11, 2012 purchase agreement through which Fund III acquired PCA had representations and warranties concerning PCA's compliance with the AKS: "No managers, directors, partners, members, equity owners or officers of the Company nor any of their respective agents or employees has directly or indirectly made or offered to make, or solicited or received, any contribution, gift, bribe, rebate, payoff, influence payment, kickback or any inducement . . . in violation of the federal Anti-Kickback Statute." The purchase agreement was signed by Glouchevitch.

157. When Patrick Smith became CEO of PCA in March 2014, he knew or should have known, from his past experience as CEO of two health care companies, about statutes regulating the health care industry, including the AKS.

158. When Matthew Smith was hired to lead the topical compounding business in April 2014, his prior experience included evaluating health care providers' compliance with federal health care program requirements, which include compliance with the AKS.

159. In addition, PCA's compliance training dated January 2014 instructed that the AKS prohibits paying remuneration to induce a referral for any item or service reimbursed by a federal health care program.

160. PCA's employee handbook dated January 2014 notes that the "anti-kickback statute is a federal law prohibiting persons from willfully offering, paying, seeking, or receiving anything of value to bring about a referral for medical services or goods payable under Medicare or Medicaid. . . . This law prohibits kickbacks and bribes." It also warned that "[r]outine waivers of co-insurance or deductibles for reasons other than real financial hardship" are "illegal under the anti-kickback statute." RLH received a copy of PCA's January 1, 2014 employee handbook.

161. In April 2014, RLH partner Glouchevitch sent Patrick Smith the "OIG guidelines" regarding copayment waivers, which alert health care providers that routine copayment waivers could violate the AKS. Glouchevitch knew that providers had to make a good faith attempt to verify a patient's actual financial condition before agreeing to waive a copayment.

162. In May 2014, Matthew Smith sent Patrick Smith a PowerPoint presentation entitled "Hot Topics in Compounding Laws and Regulations" prepared by a law firm specializing in health care law. The presentation directs that pharmacies using marketing representatives to market and advertise compound prescriptions "[m]ust still comply with the Anti-Kickback Statute." It further advises that the following practices subject a pharmacy to heightened scrutiny and/or violate the AKS: compensating 1099 contractors "purely on commissions"; using an outside marketing company with no "SOPs" or standard operating procedures; and using marketing representatives who are paying doctors to write prescriptions for the pharmacy.

163. In June 2014, PCA employee Ada Lopez, at Matthew Smith's direction, attended an outside training course, which warned that using marketers to generate compounding prescriptions could violate the AKS and not collecting copayments due from patients constitutes

a kickback and is a crime. Ms. Lopez relayed the information she learned about the AKS to Matthew Smith when she returned from the training.

164. PCA's contract with TeleMedTech reflects PCA's familiarity with the AKS, the FCA, and other laws regulating the health care industry, which the parties agreed would govern TeleMedTech's services on behalf of PCA.

165. PCA, RLH, Patrick Smith, and Matthew Smith were also advised by counsel that paying commissions to marketers could violate the AKS.

166. In summer of 2014, attorney David Corcoran communicated to Patrick Smith and Matthew Smith that the company should not be billing government programs for prescriptions referred by the marketers. Mr. Corcoran also advised PCA that it should not pay doctors or allow independent marketers to pay third-party referral sources.

167. When Mr. Corcoran learned in late December 2014 that TRICARE was the source of a majority of the compounding revenue, he expressed concern to Patrick Smith and recommended that Mr. Smith seek further advice from an experienced health care attorney.

168. On January 20, 2015, Patrick Smith spoke to health care attorney John Morrone, who conveyed that commission arrangements with independent contractors were highly suspect, if not outright illegal, and would not fall under the "bona fide" employee exception to the AKS.

169. On January 23, 2015, Hubbs sent a calendar invite containing an agenda for the PCA board of directors meeting scheduled to take place on January 27, 2015. At the top of the email was a note that indicated that "Stark laws prohibit third party incentive payments for Rx referrals."

170. On February 10, 2015, the audit committee of PCA's board of directors received a report from a third-party auditor, Marcum LLP, recommending that the company obtain legal

advice to determine whether the marketer arrangements violated the AKS. Hubbs was a member of PCA's audit committee and RLH received a copy of the report. In a section entitled "Significant Risks," Marcum Partner Michael A. Curto wrote:

> [PCA's] compounding business has grown significantly during 2014. Significant portions of this revenue growth are the result of marketing agreements with third parties, who perform certain marketing and business development services for the Company. Payment under these marketing agreements is generally based on a percentage of net revenues collected on referrals received from referral sources developed by the third party. We strongly suggest that if the Company has not already done so, that the Company pursue a legal opinion to assure that these agreements, and the Company's actions under these agreements, are not in direct conflict with Federal laws, including but not limited to the Anti-Kickback Statute (AKS).
>
> The AKS provides that it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals or items or services reimbursable by the Federal health care system (Medicare, Medicaid or other Federal health care programs).

171. On February 17, 2015, Hubbs was introduced to an attorney from the law firm Quarles & Brady LLP. Hubbs passed the contact on to Glouchevitch, noting that the attorney had "provided good counsel and advice on the topic" of "topical pain therapies and working with independent marketing/business development firms." Glouchevitch responded, "Is there a big cautionary message coming? I fear yes." Hubbs, Glouchevitch, Patrick Smith, and Matthew Smith spoke with the Quarles & Brady LLP attorney on or about February 19 and 20, 2015, but ultimately did not engage him.

172. On or about February 23, 2015, Patrick Smith and Glouchevitch spoke to health care attorney David Matyas, who understood the call was because PCA and RLH were concerned about the legality of PCA's relationships with the marketers. Hubbs was either present on the call or was informed of the substance of the call. On the call, Patrick Smith asked Mr. Matyas if the arrangements with independent contractors who received commissions from

PCA violated the AKS. Mr. Matyas discussed the U.S. Department of Health and Human Services Office of Inspector General's views of independent sales arrangements, that paying commissions to independent sales representatives was problematic due to the AKS, that the AKS carried criminal penalties, and that PCA's marketers needed to be converted to bona fide employees to qualify for the exception to the AKS.

173. On March 3, 2015, Mr. Matyas sent Patrick Smith and Corcoran a summary of "why under the anti-kickback statute, having an employment relationship is a key to minimizing exposure." He explained that "the Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce referrals or services reimbursable by the federal or state health care programs." He noted that one statutory exception is payments by an employer to an employee under a bona fide employment relationship. Therefore, he indicated that "if these individuals are characterized as having a W-2 employment relationship with PCA, then you should take comfort that the incentive payments are otherwise protected from prosecution under the Anti-Kickback statute."

174. In response to counsel's advice to PCA, and with RLH's knowledge and approval, in early March 2015, PCA informed the marketers that they would need to convert to W-2 employees and sent them new draft employment agreements.

175. PCA and the marketers did not act quickly to convert the marketers to W-2 employees, however, because they knew by March 2015 that the existing TRICARE reimbursement system for compounded drugs would remain in effect only through April 2015. PCA and the marketers therefore aimed to make as much money as possible under the existing independent contractor agreements before May 2015.

176. On March 14, 2015, RLH partner Glouchevitch forwarded to Hubbs, Patrick Smith and Matthew Smith the public announcement that TRICARE planned to implement a screening process to ensure coverage for all ingredients in compounded drugs beginning on May 1, 2015. In forwarding the email, Mr. Glouchevitch commented that he "would expect serious changes in TRICARE reimbursement to occur." Matthew Smith, concurred, responding to the group and describing the change as a "game around decreasing reimbursement rates," and "just an excuse to support the cost cutting measures." In a separate email, Glouchevitch described the announcement as "sobering information."

177. Referencing the "changes coming up in Tricare," on March 30, 2015, Steve Miller of TeleMedTech "ask[ed] that things remain status quo (1099) while we spend most of April beating our collective heads against the wall to get this done :)"

178. PCA did, in fact, maintain the status quo with MG Ten, TeleMedTech, and MDataRx. Of those marketers, only Monty Grow, the owner and operator of MG Ten, ultimately signed an employment agreement, and that agreement was not signed until April 29, 2015.

179. PCA significantly escalated its efforts to submit kickback-tainted claims to TRICARE following the March 14, 2015 announcement. For example, TRICARE paid approximately $73 million to PCA for claims referred by the three marketers and billed in the seven months between September 1, 2014 and April 29, 2015. Of this, nearly half the amount TRICARE paid, $36 million, was for claims submitted in the six weeks after the March 14, 2015 TRICARE announcement.

180. When TRICARE reimbursements for compounded drugs dramatically decreased in May 2015, PCA stopped paying commissions to its marketers.

181. When CBS News made inquiries to PCA regarding compounding pharmacy fraud, Defendants worked together to respond with statements that were false and misleading. Patrick Smith, for example, emphasized that PCA would not tolerate efforts to jeopardize the physician-patient relationship and claimed the pharmacy was focused on the "best possible clinical outcome." Patrick Smith also recorded statements that falsely stated PCA worked closely with physicians to tailor medicines to patients' needs; falsely stated that PCA received prescriptions only from doctors; and falsely suggested that PCA required patients to make their copayments.

H. RLH and PCA Failed to Implement Any Compliance Measures Over the Topical Compounding Business

182. Despite Defendants' knowledge of the AKS, as reflected in PCA's own employee handbook (with which RLH was familiar), Defendants took no substantial steps to implement compliance oversight of PCA's topical compounding business.

183. Even though RLH touted its commitment to "corporate governance" and the "standards we expect of our portfolio companies," as of September 2014, there no was no compliance officer at PCA.

184. In December 2014, the Board interviewed Joe Dimond for the position of Director of Corporate Compliance and subsequently selected him for the position in January 2015. Dimond had no education, training, or experience in compliance.

185. Despite his position as Director of Corporate Compliance, Dimond had no authority over the compounding business.

186. Dimond was aware that, among other things, marketers were submitting prescriptions directly to PCA, but he did not question these practices or take any action to address them.

187. RLH did not consider establishing a compliance committee or hiring a dedicated chief compliance officer until after the CBS story ran regarding the abuses in the topical compounding business.

188. A consulting company that reviewed compliance measures at PCA determined, as a result of an on-site assessment conducted in December 2015, that "PCA's Compliance Program lacked the fundamental seven (7) elements of an effective compliance program as set forth by the OIG HHS, particularly the education and training elements."

I. Compliance With The Anti-Kickback Statute And Patient-Prescriber Laws Is Material To The Government's Reimbursement Decision

189. Compliance with the AKS and a valid patient-prescriber relationship are material to the government's decision to reimburse a pharmacy for prescription drugs for TRICARE patients.

190. As a condition of payment by TRICARE, a pharmacy must comply with the AKS and must not offer or pay anything of value to third parties in exchange for referring, arranging, or recommending TRICARE patients for prescriptions to be filled by the pharmacy and reimbursed by TRICARE. *See* 32 C.F.R. § 199.9.

191. In its Provider Agreement with ESI, PCA falsely agreed that it would comply with all applicable fraud, waste and abuse laws, which include the AKS and the FCA. PCA's agreement to comply with all applicable fraud, waste, and abuse laws was material to its continued participation in the TRICARE prescription benefit program administered by ESI.

192. PCA's compliance with the AKS goes to the very essence of the bargain between PCA and the TRICARE program. When DHA pays a pharmacy for drugs prescribed for a TRICARE patient, it does so with the expectation that the prescription is not compromised by illegal kickbacks, which may taint medical decision-making and increase health care costs. AKS

violations are not minor, insubstantial, or mere technicalities that are not relevant DHA's payment decisions.

193. Congress's enactment of 42 U.S.C. § 1320a-7b(g) reflects Congress's determination that violations of the AKS are material under the AKS.

194. Defendants knew that compliance with the AKS was a condition of payment and material requirement for receiving TRICARE reimbursement.

195. The Department of Justice frequently brings criminal charges and civil FCA claims against health care providers based on noncompliance with the AKS in the submission of claims to federal health care programs.

196. In addition to seeking redress through this civil FCA litigation, the government has pursued parallel criminal charges against marketers and physicians involved in the conduct alleged in this complaint.

197. On February 5, 2018, a federal jury in Miami convicted marketer Monty Grow of MG Ten of 18 criminal charges for his participation in a scheme to defraud the TRICARE program, including 13 counts of unlawful receipt of health care kickbacks in violation of the AKS based on Grow's receipt of commission payments from PCA in exchange for referral of patients to PCA for compounded drugs, as well as conspiracy to commit health care fraud, conspiracy to pay and receive health care kickbacks, and money laundering. On April 17, 2018, Grow was sentenced by United States District Judge Federico A. Moreno to a 262-month prison term and ordered to pay approximately $18 million in restitution. *United States v. Grow*, No. 16-20893-Cr-Moreno (DE 208).

198. In addition, eight other marketers for MG Ten have pleaded guilty to their involvement in the kickback scheme with PCA, have been sentenced, and have been ordered to

pay restitution and/or criminal penalties. *See United States v. Halliburton*, No. 16-20846-Cr-Huck (DE 37); *United States v. Bear*, No. 16-20910-Cr-Scola (DE 72); *United States v. Robinson*, No. 16-20910-Cr-Scola (DE 69); *United States v. Dutting*, No. 16-20910-Cr-Scola (DE 57); *United States v. Lay*, No. 16-20893-Cr-Moreno (DE 181); *United States v. Bowman*, No. 16-60248-Cr-Gayles (DE 31); *United States v. Bjerke*, No. 17-60264-Cr-Cohn (DE 20); *United States v. Matthews*, No. 17-20463-Cr-Gayles (DE 33).

199. One of PCA's top prescribing physicians, Dr. Paul Matthew Bolger, has also pleaded guilty to 19 counts of false statements relating to health care matters and five counts of introduction of misbranded drugs; Dr. Bolger admitted to signing prescriptions for compounded drugs, for which PCA billed and received payment from TRICARE, when the prescriptions contained materially false statements that he had reviewed the patients' medical records and determined the drugs were medically necessary, when in fact, he had not spoken to the patients, reviewed the patients' medical records, or established a valid doctor-patient relationship with the patients. On February 22, 2019, Dr. Bolger was sentenced to a 24-month prison term and ordered to pay approximately $1.6 million in restitution.

200. Fourteen members of the military have been subjected to non-judicial punishment, including reduction in rank and forfeiture of pay, for accepting kickbacks in connection with the PCA scheme; another, a Lieutenant Commander, pleaded guilty to a violation of the Uniform Code of Military Justice due to his recruitment of patients for PCA in return for kickbacks; and six others have agreed to repay DHA the amount they received in kickbacks in connection with PCA.

201. A valid patient-prescriber relationship is also important to the government's decision to reimburse a pharmacy for drugs prescribed for TRICARE patients.

202. As a condition of payment by TRICARE, a pharmacy must comply with applicable state laws, including laws requiring that a prescription arise from a valid patient-prescriber relationship that includes a physical examination of the patient. *See* 32 C.F.R. § 199.6(d)(3).

203. A prescriber who is directly involved in a patient's care is expected to prescribe drugs that are medically necessary and appropriate for the patient. The importance of a sufficient physical evaluation of the patient to TRICARE's decision to reimburse health care services provided to that patient is evident in TRICARE's telemedicine policy, which requires, among other things, that the practitioner performing the telemedicine visit be able to see the patient through interactive audio and video communication, and excludes from coverage services provided through an audio-only telephone. TRICARE Policy Manual 6010.57-M, Ch. 7, Sec. 22.1 (Feb. 1, 2008); TRICARE Policy Manual 6010.60-M, Ch. 7, Sec. 22.1 (April 1, 2015).

204. DHA has audited pharmacies and recouped payments for compounded drugs for TRICARE patients for whom it has no record of a health care visit to the prescribing physician or other provider proximate to the writing of the prescription.

205. DHA has exercised its authority to suspend providers under investigation for fraud and abuse, including the payment of kickbacks.

206. TRICARE was unaware of the Defendants' conduct during the period from September 1, 2014 to April 29, 2015.

207. No person or entity on PCA's behalf sought approval from DHA/TRICARE for PCA's payments to third-party marketers of a percentage of PCA's profit on TRICARE reimbursements for compounded drugs or for PCA's use of purported charities associated with

marketers to fund part of the copayment owed for prescriptions for compounded drugs for TRICARE beneficiaries.

208. TRICARE would have refused to pay PCA's claims had it known they did not arise from valid patient-prescriber relationships and were tainted by the pharmacy's kickbacks to marketers and funding of patients' copayments.

J. The United States Suffered Damages

209. TRICARE paid PCA approximately $72 million for prescriptions illegally induced by kickbacks to MG Ten, TeleMedTech, and MDataRx from September 1, 2014 to April 29, 2015, when the first and only one of the top three marketers (Monty Grow of MG Ten) signed an employment agreement. In this time period, PCA submitted approximately 10,800 paid claims to TRICARE for prescriptions referred by MG Ten, TeleMedTech, and MDataRx.

210. TRICARE paid PCA approximately $16 million for prescriptions illegally induced by kickbacks in the form of PCA's and TeleMedTech's funding of patients' copayments.

K. Representative Claims

211. The following claims are representative examples of the approximately 10,800 paid claims submitted by PCA that were referred by one of the three marketers.

1. Representative Claim 1: Patient RR

212. RR was a patient referred to PCA by Monty Grow of MG Ten pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

213. Prescription 107367 is a prescription for scar cream written by prescriber Sara Garcia for patient RR dated January 27, 2015. Garcia signed the prescription without ever examining RR.

214. On January 28, 2015, MG Ten faxed prescription 107367 to PCA. The fax was received by Matthew Smith, among others.

215. On January 28, 2015, PCA filled prescription 107367 and submitted the claim to TRICARE, which processed the claim that same day.

216. On February 13, 2015, PCA made a wire transfer payment to MG Ten in the amount of $1,964,740.80, of which $7,696.67 was a kickback for referral of prescription 107367 to PCA by Monty Grow.

217. On February 18, 2015, TRICARE paid PCA $16,555.55 for prescription 107367.

218. In the January 28, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 107367, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on January 27, 2015, and filled on January 28, 2015; (2) that the prescription number was 107367; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was RR (along with other information identifying the patient, such as a patient's identification number, zip code, and date of birth); (5) that the drug was prescribed by Sara Garcia by disclosing the prescriber's identification number (1275529604) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number (1417978479); (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($19,464.82), and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 360 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLUTICASONE PROPIONATE POWDER, NDC No. 38779276004, in a quantity of 3.601 grams;

- LEVOCETIRIZINE DIHYDROCHL PWDR, NDC No. 38779278209, in a quantity of 7.201 grams;
- PENTOXIFYLLINE POWDER, NDC No. 38779256009, in a quantity of 1.801 grams;
- PRILOCAINE HCL POWDER, NDC No. 52372808050, in a quantity of 10.801 grams;
- GABAPENTIN POWDER, NDC No. 38779246109, in a quantity of 54 grams;
- PRACASIL TM-PLUS GEL, NDC No. 51927465500, in a quantity of 246.6 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 38779190301, in a quantity of 36 grams.

219. Although PCA made these and other representations in its reimbursement claim for prescription 107367, PCA did not disclose along with the claim or otherwise that prescription 107367 was referred to PCA by Monty Grow pursuant to an illegal kickback scheme or that there was not a valid patient-prescriber relationship between RR and Sara Garcia.

220. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

221. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

222. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

223. Because of the lack of a valid patient-prescriber relationship, prescription 107367 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

224. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

225. PCA knowingly submitted the January 28, 2015 claim for reimbursement to TRICARE on prescription 107367, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

2. Representative Claim 2: Patient JC

226. JC was a patient referred to PCA by Monty Grow of MG Ten pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

227. Prescription 107271 is a prescription for scar cream written by prescriber Long Hoang for patient JC dated January 26, 2015. Hoang signed the prescription without ever examining JC.

228. On January 26, 2015, MG Ten faxed prescription 107271 to PCA. The fax was received by Matthew Smith, among others.

229. On January 27, 2015, PCA filled prescription number 107271 and submitted the claim to TRICARE, which processed the claim that same day.

230. On February 13, 2015, PCA made a wire transfer payment to MG Ten in the amount of $1,964,740.80, of which $7,697.59 was a kickback for referral of prescription 107271 to PCA by Monty Grow.

231. On February 18, 2015, TRICARE paid PCA $16,557.39 for prescription 107271.

232. In the January 27, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 107271, PCA made certain specific representations about the goods

or services it provided. There representations include, among other things, (1) that the prescription was written on January 26, 2015, and filled on January 27, 2015; (2) that the prescription number was 107271; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was JC (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Long Hoang by disclosing the prescriber's identification number (1861694424) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($19,464.82), and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 360 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLUTICASONE PROPIONATE POWDER, NDC No. 38779276004, in a quantity of 3.601 grams;
- LEVOCETIRIZINE DIHYDROCHL PWDR, NDC No. 38779278209, in a quantity of 7.201 grams;
- PENTOXIFYLLINE POWDER, NDC No. 38779256009, in a quantity of 1.801 grams;
- PRILOCAINE HCL POWDER, NDC No. 52372808050, in a quantity of 10.801 grams;
- GABAPENTIN POWDER, NDC No. 38779246109, in a quantity of 54 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 58597807801, in a quantity of 36 grams;
- PRACASIL TM-PLUS GEL, NDC No. 51927465500, in a quantity of 246.6 grams.

233. Although PCA made these and other representations in its reimbursement claim for prescription 107271, PCA did not disclose along with the claim or otherwise that prescription

107271 was referred to PCA by Monty Grow pursuant to an illegal kickback scheme, or that there was not a valid patient-prescriber relationship between JC and Long Hoang.

234. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

235. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

236. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

237. Because of the lack of a valid patient-prescriber relationship, prescription 107271 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

238. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

239. PCA knowingly submitted the January 27, 2015 claim for reimbursement to TRICARE on prescription 107271, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

3. Representative Claim 3: Patient RR1

240. RR1 was a patient referred to PCA by Monty Grow of MG Ten pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

241. Prescription 114075 is a prescription for scar cream written by prescriber Thomas John for patient RR1 and dated March 27, 2015. John signed the prescription without ever examining RR1.

242. On March 28, 2015, MG Ten faxed prescription 114075 to PCA. The fax was received by Matthew Smith, among others.

243. On April 6, 2015, PCA filled prescription 114075 and submitted the claim to TRICARE, which processed the claim that same day.

244. On April 27, 2015, PCA made a wire transfer payment to MG Ten in the amount of $1,832,268.40, of which $8,784.28 was a kickback for referral of prescription 114075 to PCA by Monty Grow.

245. On April 29, 2015, TRICARE paid PCA $18,230.29 for prescription 114075.

246. In the April 6, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 114075, PCA made specific representations about the goods or services it provided. There representations include, among other things, (1) that the prescription was written on March 27, 2015, and filled on April 6, 2015; (2) that the prescription number was 114075; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was RR1 (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Thomas John by disclosing the prescriber's identification number (1013095603) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($21,438.64), and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 360 grams; (10) that the

prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLUTICASONE PROPIONATE POWDER, NDC No. 38779276004, in a quantity of 3.601 grams;
- LEVOCETIRIZINE DIHYDROCHL PWDR, NDC No. 38779278209, in a quantity of 7.201 grams;
- PENTOXIFYLLINE POWDER, NDC No. 38779256009, in a quantity of 1.801 grams;
- PRILOCAINE HCL POWDER, NDC No. 52372808050, in a quantity of 10.801 grams;
- GABAPENTIN POWDER, NDC No. 52372091210, in a quantity of 54 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 58597807801, in a quantity of 36 grams;
- PRACASIL TM-PLUS GEL, NDC No. 51927465500, in a quantity of 246.6 grams.

247. Although PCA made these and other representations in its reimbursement claim for prescription 114075, PCA did not disclose along with the claim or otherwise that prescription 114075 was referred to PCA by Monty Grow pursuant to an illegal kickback scheme, or that there was not a valid relationship between RR1 and Thomas John, the provider who prescribed the medication.

248. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

249. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

250. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

251. Because of the lack of a valid patient-prescriber relationship, prescription 114075 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

252. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

253. PCA knowingly submitted the April 6, 2015 claim for reimbursement to TRICARE on prescription 114075, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

4. Representative Claim 4: Patient JL

254. JL was a patient referred to PCA by Erik Santos of MDataRx pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210 .

255. Prescription 108285 is a prescription written for a compound of "metabolic" vitamins and dietary supplements by prescriber Vinson Disanto for patient JL dated February 18, 2015. Disanto signed the prescription without ever examining JL.

256. On February 18, 2015, Erik Santos emailed prescription 108285 to PCA.

257. On February 21, 2015, PCA filled prescription 108285 and submitted the claim to TRICARE, which processed the claim that same day.

258. On February 27, 2015, PCA made a wire transfer payment to MDataRx in the amount of $457,099.86, of which $8,040.66 was a kickback for referral of prescription 108285 to PCA by Erik Santos.[1]

[1] This amount reflects a 65% commission rate for referral of prescription 108285.

259. On March 18, 2015, TRICARE paid PCA $12,435.98 for prescription 108285.

260. In the February 21, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 108285, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on February 18, 2015, and filled on February 21, 2015; (2) that the prescription number was 108285; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was JL (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Vinson Disanto by disclosing the prescriber's identification number (1932300134) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($14,586.54) and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 60 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- COENZYME Q-10 POWDER, NDC No. 38779245809, in a quantity of 5.401 grams;
- LIPOIC ACID POWDER, NDC No. 52372088704, in a quantity of 12 grams;
- VITAMIN D3 100,000 UNIT/GM PWD, NDC No. 52372086302, in a quantity of 0.6 grams;
- METHYLCOBALAMIN POWDER, NDC No. 38779197405, in a quantity of 0.6 grams;
- PYRIDOXAL-5-PHOSPHATE POWDER, NDC No. 52372078303, in a quantity of 3.217 grams;
- RESVERATROL POWDER, NDC No. 51927436700, in a quantity of 15 grams;
- FOLIC ACID POWDER, NDC No. 52372090310, in a quantity of 0.06 grams;

- FREEDOM SIMPLECAP POWDER, NDC No. 52372067803, in a quantity of 0.18 grams;

261. Although PCA made these and other representations in its reimbursement claim for prescription 108285, PCA did not disclose along with the claim or otherwise that prescription 108285 was referred to PCA by Erik Santos pursuant to an illegal kickback scheme or that there was not a valid patient-prescriber relationship between JL and Vinson Disanto.

262. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

263. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

264. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

265. Because of the lack of a valid patient-prescriber relationship, prescription 108285 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

266. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

267. PCA knowingly submitted the February 21, 2015 claim for reimbursement to TRICARE on prescription 108285, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

5. Representative Claim 5: Patient KT

268. KT was a patient referred to PCA by Erik Santos of MDataRx pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

269. Prescription 106433 is a prescription for scar cream written by prescriber Vinson Disanto for patient KT dated January 14, 2015. Disanto signed the prescription without ever examining KT.

270. On January 16, 2015, Erik Santos emailed prescription 106433 to PCA. The email was received by Matthew Smith, among others.

271. On January 16, 2015, PCA filled prescription 106433 and submitted the claim to TRICARE, which processed the claim that same day.

272. On January 30, 2015, PCA made a wire transfer payment to MDataRx in the amount of $928,955.80, of which $7,615.87 was a kickback for referral of prescription 106433 to PCA by Erik Santos. [2]

273. On February 4, 2015, TRICARE paid PCA $12,246.33 for prescription 106433.

274. In the January 16, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 106433, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on January 14, 2015, and filled on January 16, 2015; (2) that the prescription number was 106433; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was KT (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Vinson Disanto by disclosing the prescriber's identification number (1932300134) and last name; (6) that the

[2] This amount reflects a 65% commission rate for referral of prescription 106433.

drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($14,395.17) and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 240 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLUTICASONE PROPIONATE POWDER, NDC No. 38779276004, in a quantity of 2.4 grams;
- LEVOCETIRIZINE DIHYDROCHL PWDR, NDC No. 38779278209, in a quantity of 4.8 grams;
- PENTOXIFYLLINE POWDER, NDC No. 38779256009, in a quantity of 1.2 grams;
- PRILOCAINE HCL POWDER, NDC No. 52372808050, in a quantity of 7.201 grams;
- GABAPENTIN POWDER, NDC No. 38779246109, in a quantity of 36 grams;
- PRACASIL TM-PLUS GEL, NDC No. 51927465500, in a quantity of 164.401 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 58597807801, in a quantity of 24 grams.

275. Although PCA made these and other representations in its reimbursement claim for prescription 106433, PCA did not disclose along with the claim or otherwise that prescription 106433 was referred to PCA by Erik Santos pursuant to an illegal kickback scheme or that there was not a valid patient-prescriber relationship between KT and Vinson Disanto.

276. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

277. In its provider agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

278. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

279. Because of the lack of a valid patient-prescriber relationship, prescription 106433 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

280. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

281. PCA knowingly submitted the January 16, 2015 claim for reimbursement to TRICARE on prescription 106433, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

6. Representative Claim 6: Patient EH

282. EH was a patient referred to PCA by Erik Santos of MDataRx pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

283. Prescription 105463 is a prescription for pain cream written by prescriber Vinson Disanto for patient EH dated December 23, 2014. Disanto signed the prescription without ever examining EH.

284. On December 26, 2014, Erik Santos emailed prescription 105463 to PCA. The email was received by Matthew Smith, among others.

285. On December 26, 2014, PCA filled prescription 105463 and submitted the claim to TRICARE, which processed the claim that same day.

286. On January 2, 2015, PCA made a wire transfer payment to MDataRx in the amount of $865,249.70, which included a kickback for referral of prescription 105463 to PCA by Erik Santos.

287. On January 21, 2015, TRICARE paid PCA $10,040.89 for prescription 105463.

288. In the December 26, 2014 claim for reimbursement that PCA submitted to TRICARE for prescription 105463, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on December 23, 2014, and filled on December 26, 2014; (2) that the prescription number was 105463; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was EH (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Vinson Disanto by disclosing the prescriber's identification number (1932300134) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($11,938.32) and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 240 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLUTICASONE PROPIONATE POWDER, NDC No. 38779276004, in a quantity of 2.4 grams;
- LIDOCAINE HCL POWDER, NDC No. 38779008209, in a quantity of 12 grams;
- GABAPENTIN POWDER, NDC No. 38779246109, in a quantity of 14.401 grams;

- CYCLOBENZAPRINE HCL POWDER, NDC No. 38779039509, in a quantity of 4.8 grams;
- STERA BASE CREAM, NDC No. 45861003400, in a quantity of 182.401 grams;
- ETHOXY DIGLYCOL REAGENT, NDC No. 52372073702, in a quantity of 24 grams.

289. Although PCA made these and other representations in its reimbursement claim for prescription 105463, PCA did not disclose along with the claim or otherwise that prescription 105463 was referred to PCA by Erik Santos pursuant to an illegal kickback scheme or that there was not a valid patient-prescriber relationship between EH and Vinson Disanto.

290. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

291. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

292. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

293. Because of the lack of a valid patient-prescriber relationship, prescription 105463 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

294. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

295. PCA knowingly submitted the December 26, 2014 claim for reimbursement to TRICARE on prescription 105463, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

7. Representative Claim 7: Patient EP

296. EP was a patient referred to PCA by Steve Miller of TeleMedTech pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

297. Prescription 110563 is a prescription for pain cream written by prescriber Vijil Rahulan, for patient EP dated February 24, 2015. Rahulan signed the prescription without ever examining EP.

298. On February 28, 2015, Rahulan and/or TeleMedTech faxed prescription 110563 to PCA. The fax was received by Matthew Smith, among others.

299. On March 9, 2015, PCA filled prescription 110563 and submitted the claim to TRICARE, which processed the claim that same day.

300. Pursuant to the PFARN scheme detailed above, PCA did not collect the required $20 copayment from EP but rather billed PFARN for EP's copayment.

301. On March 27, 2015, PCA made a wire transfer payment to TeleMedTech in the amount of $1,217,811.10, of which $1,997.83 was a kickback for referral of prescription 110563 to PCA by Steve Miller.

302. On April 12, 2015, TRICARE paid PCA $4,564.18 for prescription 110563.

303. In the March 9, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 110563, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on February 24, 2015, and filled on March 9, 2015; (2) that the prescription number was

110563; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was EP (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Vijil Rahulan by disclosing the prescriber's identification number (1710953666) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($5,319.92) and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 240 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- BUPIVACAINE HCL POWDER, NDC No. 38779052409, in a quantity of 4.8 grams;
- CYCLOBENZAPRINE HCL POWDER, NDC No. 38779039509, in a quantity of 4.8 grams;
- FLURBIPROFEN POWDER, NDC No. 52372084307, in a quantity of 36 grams;
- LIDOCAINE HCL POWDER, NDC No. 38779008209, in a quantity of 12 grams;
- HYALURONIC ACID SOD SALT POWD, NDC No. 51927170500, in a quantity of 0.48 grams;
- STERA BASE CREAM, NDC No. 45861003400, in a quantity of 181.92 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 38779190301, in a quantity of 24 grams.

304. Although PCA made these and other representations in its reimbursement claim for prescription 110563, PCA did not disclose along with the claim or otherwise that prescription 110563 was referred to PCA by Steve Miller pursuant to an illegal kickback scheme, that there was not a valid patient-prescriber relationship between EP and Vijil Rahulan, or that EP did not pay the copayment amount pursuant to the PFARN scheme.

305. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

306. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

307. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

308. Because of the lack of a valid patient-prescriber relationship, prescription 110563 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

309. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

310. PCA submitted the March 9, 2015 claim for reimbursement to TRICARE on prescription 110563, and RLH, Patrick Smith, and Matthew Smith caused the submission of this claim as alleged in paragraphs 1 through 210 above.

8. Representative Claim 8: Patient MC

311. MC was a patient referred to PCA by Steve Miller of TeleMedTech pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

312. Prescription 111021 is a prescription for pain cream written by prescriber Paul Bolger for patient MC dated March 4, 2015. Bolger signed the prescription without ever

examining EP. In the prescription, Bolger falsely attested that "I have reviewed my patient's medical record(s) and determine that the items I have ordered are medically necessary."

313. On March 5, 2015, Bolger and/or TeleMedTech emailed prescription 111021 to PCA. The fax was received by Matthew Smith, among others.

314. On March 10, 2015, PCA filled prescription 111021 and submitted the claim to TRICARE, which processed the claim that same day.

315. Pursuant to the PFARN scheme detailed above, PCA did not collect the required $20 copayment from MC but rather billed PFARN for MC's copayment.

316. On March 27, 2015, PCA made a wire transfer payment to TeleMedTech in the amount of $1,217,811.10, of which $2,182.51 was a kickback for referral of prescription 111021 to PCA by Steve Miller.

317. On April 12, 2015, TRICARE paid PCA $4,764.76 for prescription 111021.

318. In the March 10, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 111021, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on March 4, 2015, and filled on March 10, 2015; (2) that the prescription number was 111021; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was MC (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Paul Bolger by disclosing the prescriber's identification number (1376516609) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($5,588.72) and the Average Wholesale Price of the individual ingredients; (8) that the drug

dispensed was a compound; (9) that the compound was, in total, 240 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- FLURBIPROFEN POWDER, NDC No. 52372084307, in a quantity of 24 grams;
- GABAPENTIN POWDER, NDC No. 52372091210, in a quantity of 24 grams;
- LIDOCAINE HCL POWDER, NDC No. 38779008209, in a quantity of 12 grams;
- AMITRIPTYLINE HCL POWDER, NDC No. 63275993609, in a quantity of 4.8 grams;
- HYALURONIC ACID SOD SALT POWD, NDC No. 51927170500, in a quantity of 0.48 grams;
- STERA BASE CREAM, NDC No. 45861003400, in a quantity of 150.72 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 38779190301, in a quantity of 24 grams.

319. Although PCA made these and other representations in its reimbursement claim for prescription 111021, PCA did not disclose along with the claim or otherwise that prescription 111021 was referred to PCA by Steve Miller pursuant to an illegal kickback scheme, that there was not a valid patient-prescriber relationship between MC and Paul Bolger, or that MC did not pay the required copayment amount pursuant to the PFARN scheme.

320. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

321. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

322. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

323. Because of the lack of a valid patient-prescriber relationship, prescription 111021 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

324. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

325. PCA knowingly submitted the March 10, 2015 claim for reimbursement to TRICARE on prescription 111021, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

9. Representative Claim 9: Patient MC1

326. MC1 was a patient referred to PCA by Steve Miller of TeleMedTech pursuant to the illegal kickback scheme detailed above in paragraphs 1 through 210.

327. Prescription 114989 is a prescription for pain cream written by prescriber Paul Bolger for patient MC1 dated March 31, 2015. Bolger signed the prescription without ever examining EP. In the prescription, Bolger falsely attested that "I have reviewed my patient's medical record(s) and determine that the items I have ordered are medically necessary."

328. On April 1, 2015, Bolger and/or TeleMedTech faxed prescription 114989 to PCA.

329. On April 10, 2015, PCA filled prescription 114989 and submitted the claim to TRICARE, which processed the claim that same day.

330. Pursuant to the PFARN scheme detailed above, PCA did not collect the required $20 copayment from MC1 but rather billed PFARN for MC1's copayment.

331. On April 27, 2015, PCA made a wire transfer payment to TeleMedTech in the amount of $1,809,665.34, of which $2,652.40 was a kickback for referral of prescription 114989 to PCA by Steve Miller.

332. On April 29, 2015, TRICARE paid PCA $5,873.32 for prescription 114989.

333. In the April 10, 2015 claim for reimbursement that PCA submitted to TRICARE for prescription 114989, PCA made specific representations about the goods or services it provided. These representations include, among other things, (1) that the prescription was written on March 31, 2015, and filled on April 10, 2015; (2) that the prescription number was 114989; (3) that the refill number was 0 (indicating that this was the first fill of the drug and not a refill); (4) that the patient's name was MC1 (along with other information identifying the patient, such as zip code and date of birth); (5) that the drug was prescribed by Paul Bolger by disclosing the prescriber's identification number (1376516609) and last name; (6) that the drug was dispensed by PCA by disclosing the pharmacy's NPI number, 1417978479; (7) information concerning drug pricing, including the Usual and Customary price of the compound as a whole ($6,901.04) and the Average Wholesale Price of the individual ingredients; (8) that the drug dispensed was a compound; (9) that the compound was, in total, 240 grams; (10) that the prescription was intended to be a 30-day supply; and (11) that the compound consisted of the following ingredients:

- BACLOFEN POWDER, NDC No. 38779038809, in a quantity of 4.8 grams;
- CYCLOBENZAPRINE HCL POWDER, NDC No. 38779039509, in a quantity of 4.8 grams;
- FLURBIPROFEN POWDER, NDC No. 52372084307, in a quantity of 36 grams;
- LIDOCAINE HCL POWDER, NDC No. 38779008209, in a quantity of 12 grams;

- HYALURONIC ACID SOD SALT POWD, NDC No. 51927170500, in a quantity of 0.48 grams;
- STERA BASE CREAM, NDC No. 45861003400, in a quantity of 181.92 grams;
- ETHOXY DIGLYCOL LIQUID, NDC No. 58597807801, in a quantity of 24 grams.

334. Although PCA made these and other representations in its reimbursement claim for prescription 114989, PCA did not disclose along with the claim or otherwise that prescription 114989 was referred to PCA by Steve Miller pursuant to an illegal kickback scheme, that there was not a valid patient-prescriber relationship between MC1 and Paul Bolger, or that MC1 did not pay the required copayment amount pursuant to the PFARN scheme. By virtue of this material omission, the specific representations on the claim were misleading and the claim is false or fraudulent under the False Claims Act.

335. In its Provider Agreement, PCA agreed to abide by applicable laws and regulations, including fraud, waste, and abuse laws, and to collect patient copayments.

336. Each time a claim was submitted, PCA used its Provider Agreement to obtain payment of the claim. At the time PCA did so, PCA was engaged in the illegal schemes set forth herein. The Provider Agreement – used at the time each claim was submitted – was a false statement or record material to a false claim.

337. Because of the lack of a valid patient-prescriber relationship, prescription 114989 was a false record, or contained a false statement, that PCA used in submitting, and was material to, the false claim to TRICARE.

338. The claim is also false or fraudulent under the False Claims Act by virtue of 42 U.S.C. § 1320a-7b(g), which provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

339. PCA knowingly submitted the April 10, 2015 claim for reimbursement to TRICARE on prescription 114989, and RLH, Patrick Smith, and Matthew Smith knowingly caused the submission of this claim as alleged in paragraphs 1 through 210 above.

FIRST CAUSE OF ACTION

(False or Fraudulent Claims)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

340. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 339.

341. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of the United States false or fraudulent TRICARE claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for compounded drugs for TRICARE patients that were tainted by kickbacks to marketers and patients and did not arise from a valid patient-prescriber relationship.

342. By reason of the foregoing, the United States suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CAUSE OF ACTION

(False Records or Statements Material to False Claims)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

343. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 339.

344. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements—i.e., false statements in PCA's Provider Agreement with ESI regarding compliance with the AKS, FCA, and applicable state law requiring a valid patient-prescriber relationship, and false compounded drug prescriptions that were not supported by a valid patient-prescriber relationship—material to false or fraudulent claims that were paid and approved by the TRICARE program, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

345. Defendants' false representations of compliance with the AKS, FCA, and applicable state law requiring a valid patient-prescriber relationship were material to false or fraudulent TRICARE claims, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

346. The false representations of compliance with the agreements in PCA's Provider Agreement with ESI that were made and caused to be made by Defendants were material to TRICARE's payment of the false claims.

347. The invalid prescription records were material to false or fraudulent TRICARE claims, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

348. Said false records and statements were made, used, or caused to be made or used, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

THIRD CAUSE OF ACTION

(Conspiracy)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(C))

349. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 339.

350. By virtue of the acts described above, Defendants RLH and PCA (through its executives Patrick Smith and Matthew Smith) conspired and entered into an agreement to have the United States pay false or fraudulent claims by agreeing to pay kickbacks to marketers and patients in return for prescriptions for compounded pharmaceutical products that PCA would present to TRICARE for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

351. Defendants RLH and PCA (through its executives Patrick Smith and Matthew Smith) conspired and entered into an agreement to have the United States pay false or fraudulent claims by agreeing to obtain from marketers prescriptions for compounded drugs that did not arise from a valid patient-prescriber relationship that PCA would present to TRICARE for payment or approval.

352. By virtue of the false of fraudulent claims that RLH and PCA (through its executives Patrick Smith and Matthew Smith) conspired to be made and/or caused to be made, the United States suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

FOURTH CAUSE OF ACTION

(Payment by Mistake)

353. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 339.

354. This is a claim under federal common law by the United States for the recovery of monies that TRICARE paid to PCA by mistake for compounded drugs that were tainted by kickbacks to marketers and patients and did not arise from a valid patient-prescriber relationship.

355. As a consequence of the conduct and the acts set forth above, PCA was paid by mistake by the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

FIFTH CAUSE OF ACTION

(Unjust Enrichment)

356. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 339.

357. This is a claim under federal common law by the United States for recovery of monies by which PCA has been unjustly enriched.

358. By virtue of the conduct and the acts described above, PCA was unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF AND JURY DEMAND

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

1. As to the First, Second, and Third Causes of Action (False Claims Act), against Defendants for: (i) statutory damages in an amount to be established at trial, trebled as

required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

2. As to the Fourth Cause of Action (Payment Under Mistake of Fact), for: (i) an amount equal to the money paid by the United States through the TRICARE Program to PCA, and illegally retained by PCA, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

3. As to the Fifth Cause of Action (Unjust Enrichment), for: (i) an amount equal to the money paid by the United States through the TRICARE Program to PCA, or the amount by which PCA was unjustly enriched, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

4. All other and further relief as the Court may deem just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Respectfully submitted this 18th day of March 2019.

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