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 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 prescriber-patient 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 \$68 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, 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. 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 a holding company 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" 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).
- 15. 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).
- 16. 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.
- 17. 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.

18. 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.

B. The TRICARE Program

- 19. 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.
- 20. 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.
- 21. 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.
- 22. 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 generally were paid the "average wholesale price" of each ingredient in a compounded drug minus a negotiated discount.
- 23. 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.

- 24. 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.
- 25. 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).
- 26. 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).
- 27. To receive reimbursement from TRICARE for compounded drugs, a pharmacy must enter into a Provider Agreement with ESI, TRICARE's pharmacy benefits manager.
- 28. 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.
- 29. On August 28, 2012, PCA executed a Provider Agreement with ESI in which PCA promised 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.
- 30. 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."
- 31. In addition, PCA promised in its Provider Agreement with ESI to comply with ESI's Provider Manual.
- 32. 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.
- 33. 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]."

- 34. 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).
- 35. 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 practitioner-patient 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).
- 36. As set forth below, by billing TRICARE for compounded drugs that were prescribed by practitioners who Defendants knew, or should have known, did not have a valid practitioner-patient relationship with the patients, Defendants presented, or caused to be presented, false or fraudulent claims to the TRICARE program.

V. FACTS

- A. RLH Acquired DCRX And Planned To Sell It For A Profit In Five Years
- 37. 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.
- 38. In July 2012, RLH made a controlling investment in DCRX through the private equity fund, RLH Investors III, LP. In its capacity as the manager of RLH Investors III, LP, 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.

- 39. At the time that DCRX was acquired, RLH managed other health care companies, including Avella, a specialty pharmacy similar to DCRX.
- 40. 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

- 41. 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.
- 42. 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.
- 43. 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.

- 44. 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."
- 45. 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
- 46. 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.
- 47. 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.
- 48. 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."
- 49. Based on Glouchevitch's recommendation, the board agreed to hire Patrick Smith as CEO in March 2014.

- 50. RLH directed and oversaw Patrick Smith by, among other things, obtaining his agreement to "apprise[] [RLH] as early as possible about significant developments or concerns" regarding the company, and involve RLH in "important decisions starting at an early stage in the consideration process." For example, RLH expected Patrick Smith to consult with RLH partners before 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.
- 51. 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.
- 52. 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.
 - D. PCA Paid Kickbacks To Marketers For Referring TRICARE Patients Or Arranging For Or Recommending That TRICARE Patients Order Prescriptions From The Pharmacy
- 53. By May 2014, DCRX had decided to use "independent contractors," rather than employed sales staff, to generate prescriptions for topical compounds. RLH knew and approved of this plan.

- 54. 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.
- 55. In July 2014, DCRX entered into a "Business Associate Agreement" with MDataRx, LLC, a marketing company owned and operated by Erik Santos.
- 56. 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").
- 57. In September 2014, DCRX entered into a "Consulting Agreement" with MG Ten, a marketing company owned and operated by Monty Grow.
- 58. 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.
- 59. 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.
- 60. 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."

- 61. 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.
- 62. 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."
- 63. 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.
- 64. 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."
- 65. 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."
- 66. 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.

- 67. RLH, PCA, Patrick Smith, and Matthew Smith knew that Erik Santos, Steve Miller, and Monty Grow were not employees of PCA.
- 68. Matthew Smith negotiated PCA's contracts with the companies owned by Erik Santos, Steve Miller, and Monty Grow.
- 69. 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.
- 70. 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.
- 71. 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.
- 72. 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.

- 73. 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.
- 74. During the January 27, 2015, board meeting, Patrick Smith also reported that the company had changed its operating name to Patient Care America.
- 75. 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.
- 76. 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.
- 77. 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

78. 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

TeleMedTech \$1,54	TeleMedTe	4/10/2015
TeleMedTech \$1,80	TeleMedTe	4/27/2015
TOTAL \$6,76	TOTA	

79. 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

- 80. 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.
- 81. Each month, Patrick Smith sent the prior month's financial statements to PCA's board members, including RLH partners 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

- 82. The notes to the financial statements characterized the commissions as "an agreed cost based on compounding sales."
- 83. 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.
- 84. On December 24, 2014, Patrick Smith asked RLH for cash to fund commissions as "sales are still ahead of collections," and RLH provided PCA \$2 million on January 29, 2015.

- 85. 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.
- 86. 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.
- 87. 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.
- 88. 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 health care fraud 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.
- 89. 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.
- 90. 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."

- 91. 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."
- 92. 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."
- 93. 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.
- 94. TeleMedTech's agreement with PCA expressly provided that "[t]he Marketer may represent other Clients in the Compounding pharmacy business."
- 95. 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.

- 96. 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."
- 97. 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

- 98. 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.
- 99. 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.
- 100. 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."

- 101. 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."
- 102. 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.
- 103. 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."
- 104. 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.
- 105. 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.
- 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:)"

- 107. PCA 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.
- 108. There was no verification of financial need of the patients whose copayments were funded through this scheme.
- 109. 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.
- 110. 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.
- 111. 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.
- 112. 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 Practitioner-Patient Relationship

- 113. PCA and the marketing companies, not the prescribing doctors, designed the compounds to maximize the profit on each prescription.
- 114. 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.

- 115. 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.
- 116. 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.
- 117. 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.
- 118. 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.
- 119. As a result of PCA's efforts to maximize profit, the average reimbursement amount per prescription increased over time.

- 120. 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.
- 121. 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.
- 122. 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.
- 123. 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.
- 124. 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.
- 125. 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.
- 126. 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.

- 127. The complaints also revealed that the marketers were at times misleading or harassing patients into agreeing to the prescriptions.
- 128. 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."
- 129. 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.
- 130. Even though the complaints revealed that the prescriptions were being generated by the marketers without valid patient consent or prescriber-patient relationship, PCA continued to bill for the prescriptions referred by the marketers.
- 131. 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

- 132. 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.
- 133. As an investor in health care companies, RLH knew or should have known 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.
- 134. 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.
- 135. 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.
- 136. 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.
- 137. PCA's employee handbook dated January 2014 warned that "[r]outine waivers of co-insurance or deductibles for reasons other than real financial hardship" are "illegal under the anti-kickback statute."
- 138. 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 Anti-Kickback statute. 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.

- 139. 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.
- 140. 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.
- 141. PCA's contract with TeleMedTech reflects PCA's familiarity with the Anti-Kickback Statute, the False Claims Act, and other laws regulating the health care industry, which the parties agreed would govern TeleMedTech's services on behalf of PCA.
- 142. PCA, RLH, Patrick Smith, and Matthew Smith were also advised by counsel that paying commissions to marketers could violate the AKS. 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.

- 143. 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.
- 144. 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.
- 145. On or about February 20, 2015, Patrick Smith spoke to health care attorney David Matyas, who understood that Patrick Smith contacted him because PCA and RLH were concerned about the legality of PCA's relationships with the marketers. Mr. Matyas also communicated to Patrick Smith that PCA's marketers needed to be converted to bona fide employees to qualify for the exception to the AKS.
- 146. 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.
- 147. 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.
- 148. On March 14, 2015, RLH partner Glouchevitch forwarded to 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."

- 149. 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:)"
- 150. 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.
- 151. When TRICARE reimbursements for compounded drugs dramatically decreased in May 2015, PCA stopped paying commissions to its marketers.
- 152. 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. Defendants' Conduct Was Material

- 153. 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.
- 154. In its Provider Agreement with ESI, PCA falsely promised that it would comply with all applicable fraud, waste and abuse laws, which include the AKS and the FCA. PCA's promises to comply with all applicable fraud, waste, and abuse laws were material to its continued participation in the TRICARE prescription benefit program administered by ESI.
- 155. Defendants knew that compliance with the AKS was a condition of payment and material requirement for receiving TRICARE reimbursement.
- 156. DHA has exercised its authority to suspend providers under investigation for fraud and abuse, including the payment of kickbacks.
- 157. TRICARE was unaware of the Defendants' conduct during the period from September 1, 2014 to April 29, 2015.
- 158. 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.

I. The United States Suffered Damages

159. TRICARE paid PCA approximately \$68 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 11,718 paid claims to TRICARE, the overwhelming majority of which were attributable to MG Ten, TeleMedTech, and MDataRx.¹

160. 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.

J. Representative Claims

- 161. RR was a patient referred to PCA by Monty Grow of MG Ten. PCA filled prescription 107367 for RR for scar cream and submitted it to TRICARE, which processed the claim on January 28, 2015 and paid PCA \$16,555.55 for the prescription on February 18, 2015. RR later became a marketer for Monty Grow and received kickbacks for patients she referred to PCA, including her husband and children. RR, a TRICARE beneficiary, eventually became an employee of PCA.
- 162. JC was a patient referred to PCA by Monty Grow. PCA filled prescription number 107271 for JC for scar cream and submitted it to TRICARE, which processed the claim on January 27, 2015 and paid PCA \$16,557.39 on February 18, 2015. PCA also filled prescription number 107270 for JC for pain cream and submitted it to TRICARE, which processed the claim on January 27, 2015 and paid PCA \$4,166.32 on February 18, 2015. JC later became a marketer for Monty Grow and received kickbacks for her own prescriptions. JC, a TRICARE beneficiary, eventually became an employee of PCA.

¹ In order to protect patient confidentiality, a list of PCA claims to TRICARE has not been included in this Complaint. The United States will produce this information to Defendants at their request after entry of a protective order covering protected health information.

- 163. RR1 was a patient referred to PCA by Monty Grow. PCA filled prescription number 114075 for RR1 for scar cream and submitted it to TRICARE, which processed the claim on April 6, 2015 and paid PCA \$18,230.29 on April 29, 2015. RR1 later became a marketer for Monty Grow and received kickbacks for his brother's prescriptions. RR1, a TRICARE beneficiary, eventually became an employee of PCA.
- 164. JH was a patient referred to PCA by Erik Santos of MDataRx. PCA filled prescription number 108285 for JH for scar cream and submitted it to TRICARE, which processed the claim on February 21, 2015 and paid PCA \$12,435.98 on March 18, 2015.
- 165. KT was a patient referred to PCA by Erik Santos. PCA filled prescription number 106433 for KT for scar cream and submitted it to TRICARE, which processed the claim on January 16, 2015 and paid PCA \$12,246.33 on February 4, 2015. KT, a TRICARE beneficiary, eventually became an employee of PCA.
- 166. EH was a patient referred to PCA by Erik Santos. PCA filled prescription number 105463 for EH for scar cream and submitted it to TRICARE, which processed the claim on December 26, 2014 and paid PCA \$10,040.89 on January 21, 2015.
- 167. EP was a patient referred to PCA by Steve Miller of TeleMedTech. PCA filled prescription number 110563 for EP for pain cream and submitted it to TRICARE, which processed the claim on March 9, 2015 and paid PCA \$4,564.18 on April 12, 2015. Pursuant to the scheme detailed above, PCA did not collect a copayment from EP but rather billed PFARN for EP's copayment.
- 168. MC was a patient referred to PCA by Steve Miller. PCA filled prescription number 111021 for MC for pain cream and submitted it to TRICARE, which processed the claim on March 10, 2015 and paid PCA \$4,764.76 on April 12, 2015. Pursuant to the scheme detailed

above, PCA did not collect a copayment from MC but rather billed PFARN for MC's copayment.

169. MC1 was a patient referred to PCA by Steve Miller. PCA filled prescription number 114989 for MC1 for pain cream and submitted it to TRICARE, which processed the claim on April 10, 2015 and paid PCA \$5,873.32 on April 29, 2015. Pursuant to the scheme detailed above, PCA did not collect a copayment from MC1 but rather billed PFARN for MC1's copayment.

FIRST CAUSE OF ACTION

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

- 170. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 169.
- 171. 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), amended by 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 practitioner-patient relationship.
- 172. 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

(Payment by Mistake)

- 173. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 169.
- 174. This is a claim 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 practitioner-patient relationship.
- 175. 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.

THIRD CAUSE OF ACTION

(Unjust Enrichment)

- 176. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 169.
- 177. This is a claim by the United States for recovery of monies by which PCA has been unjustly enriched.
- 178. 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 Cause 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 Second 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 Third 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.
- 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 16th day of February 2018.

CHAD A. READLER
Acting Assistant Attorney General

RANDY HUMMEL
Attorney for the United States Acting Under
Authority Conferred by 28 U.S.C. § 515
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By: /s/Susan Torres

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