Sealed

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

United States of America
ex rel. Marisela Carmen Medrano
and Ada Lopez,

Relators,

vs.

Diabetic Care Rx, LLC,
dba Patient Care America;
Riordan, Lewis & Haden, Inc.;
Patrick Smith;
Matthew Smith; and
Thomas Buscemi;

Defendants.

Civil Action No. 15-62617-CV-BLOOM

***FILED UNDER SEAL**
PURSUANT TO
31 U.S.C. § 3730(b)(2)

***FIRST AMENDED* FEDERAL CIVIL FALSE CLAIMS ACT COMPLAINT AND REQUEST FOR JURY TRIAL**

1. Marisela Carmen Medrano and Ada Lopez (hereinafter "Relators") hereby bring this action on behalf of the United States of America against Defendants Diabetic Care Rx, LLC, dba Patient Care America ("PCA"); Riordan, Lewis & Haden, Inc. ("RLH"); Patrick Smith; Matthew Smith; and Thomas Buscemi; for treble damages and civil penalties arising from Defendants' false statements and false claims in violation of the federal Civil False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, as amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), 123 Stat. 1617 *et seq.*:

INTRODUCTION AND SUMMARY OF THE FRAUD

2. On May 1, 2015, TRICARE observed: "In recent months, Military Health System costs for compounded drugs have skyrocketed from about $54 million in August 2014 to more than $330 million in March 2015." TRICARE.mil Staff, TRICARE Revises Compound Drug Coverage (May 1, 2015) (available at http://health.mil/News/Articles/2015/05/01/TRICARE-Revises-Compound-Drug-Coverage).

3. Relators Medrano and Lopez hereby disclose the identity and *modus operandi* of perhaps the single biggest perpetrator of this fraud: Diabetic Care Rx, LLC, dba Patient Care America ("PCA"), a compounding pharmacy located in Broward County, Florida.

4. From September 2014 through June 2015, PCA defrauded the U.S. Treasury of approximately $87.75 million by providing illegal kickbacks of approximately $40 million, i.e., a whopping forty-five percent (45%) of that $87.75 million, to a handful of marketing agencies, to induce them to secure patients/prescriptions for topical pain creams, scar creams, wound care creams, and metabolic supplements/capsules.

5. This payout may very well constitute the largest volume of cash kickbacks over a period of one year or less in the history of U.S. government health programs. Even without this time parameter, the amount of kickbacks involved is staggering.

6. In committing this egregious fraud, PCA preyed on one of the finest and most vulnerable segments of American society: injured American military personnel, military retirees, and their dependents/families.

7. Fraudulent waiver of co-payments is also involved. Although the telemarketing agencies representing PCA routinely told patients that they would not have to pay anything out of pocket for these creams and capsules, the compounding pharmacy routinely billed patients for co-payments. When PCA ultimately waived copayments for virtually all patients, however, it never required that patients show an inability to pay.

8. Relators have named PCA's highest executives as defendants (CEO Patrick Smith, COO Matthew Smith, and Vice-President of Sales and Marketing Thomas Buscemi), because they played an instrumental role in this fraud.

9. Similarly, Relators have named as a defendant the private equity group Riordan, Lewis & Haden, Inc. ("RLH"), PCA's majority owner, because RLH, through two of its executives (principals Michel Glouchevitch and Kenneth D. Hubbs), co-managed PCA's compounding pharmacy, conspired with it, and approved and bankrolled its specific plan to provide the kickbacks at issue.

PARTIES

10. Plaintiff, the **United States of America** (hereinafter "the Government"), funds the provision of medical care, including services for eligible citizens through TRICARE and other federal agencies and programs (hereinafter "Government programs").

11. Plaintiff/Relator **Marisela Carmen Medrano** is a person of the full age of majority domiciled and residing in Broward County, Florida, specifically at 11450 N.W. 23 Street, Plantation, Florida 33323. She was PCA's Director of Marketing from September 2, 2014 through July 8, 2015. She worked for PCA during the entire time period that it perpetrated this fraud, and has direct and independent knowledge of its details.

12. Plaintiff/Relator **Ada Lopez** is a person of the full age of majority domiciled and residing in Broward County, Florida, specifically at 3545 N.W. 114 Terrace, Coral Springs, Florida 33065. She was PCA's Reimbursement Services Manager from April 2014 through June 3, 2015. In this capacity, she reported directly to CFO Patricia Gunn and CEO Patrick Smith, handled reimbursement issues and claims adjudications, created revenue and accounts receivable reports, studied data, and conducted credentialing and software training. Prior to serving as Reimbursement Services Manager, she was IV (infusion) Lead Tech from October 2011 through April 2014. Like Medrano, she worked for PCA during the entire time period that it perpetrated this fraud, and has direct and independent knowledge of its details.

13. As former full-time employees of PCA, through their participation in meetings, e-mails, memoranda, and the like, Relators acquired extensive, first-hand, and inside knowledge of the schemes that form the basis of this Complaint. Although Relators were not part of the Executive Team that carried out the fraud, they worked closely with the Executive Team and were privy to it.

14. Notably, as PCA's Reimbursement Services Manager, Relator Lopez acquired substantial knowledge of PCA's claims submissions to TRICARE, through its pharmacy benefits manager ("PBM"), Express Scripts, Inc. In this capacity, she also regularly interacted with the Executive Team and was privy to PCA's business operations—including the kickback scheme at issue.

15. Similarly, Medrano was the company's Director of Marketing and regularly interacted with the Executive Team. Indeed, her office was located within twenty feet of the CEO's, the COO's, and the Vice-President of Marketing and Sales. Accordingly, she was also privy to PCA's business operations—including the kickback scheme at issue.

16. Defendant **Diabetic Care Rx, LLC**, dba Patient Care America (hereinafter "PCA"), is a Florida limited liability company headquartered at 11555 Heron Bay Blvd., Suite 100, Coral Springs, Florida 33076. This is the company's designated mailing address with the Florida Department of State, Division of Corporations.

17. The company was formally organized on December 13, 2005. It was formerly known, from July 2014 through February 1, 2015, as "Patient First." Prior to that, from late 2005 through mid-2014, the company was known as "DCRX Infusion."

18. The company's pharmacy operations, warehouse, and shipping center are also based in south Florida, at 5371 Hiatus Road, Sunrise, Florida 33351. This is the company's designated principal address with the Florida Department of State, Division of Corporations. PCA is licensed as a pharmacy in all fifty states and ships its products nationwide.

19. **Riordan, Lewis & Haden, Inc.** ("RLH") is an active California corporation that was formed in 2000. Its principal business address is 10900 Wilshire Blvd., Ste. 850, Los Angeles, CA 90024 (tel. 310-405-7200). It has an additional office in California and one near Chicago: 18300 Von Karman Ave., Ste. 730, Irvine, CA 92612 (tel. 949-428-2200), and 300 E. 5th Ave., Ste. 390, Naperville, IL 60563 (tel. 949-428-2208).

20. Defendant **Patrick Smith** is a person of the full age of majority, upon information and belief, domiciled and residing in Palm Beach County, Florida. At all relevant times herein, he has been the PCA's President and Chief Executive Officer.

21. Defendant **Matthew Smith** is a person of the full age of majority, upon information and belief, domiciled and residing in Palm Beach County, Florida. At all relevant times herein, he has been PCA's COO.

22. Defendant **Thomas Buscemi** is a person of the full age of majority, upon information and belief, domiciled and residing in Harford County, Maryland. At all relevant times herein, he has been PCA's Vice-President of Sales and Marketing.

JURISDICTION, VENUE AND DISCLOSURE STATEMENT

23. Relators previously submitted to the Attorney General of the United States and the U.S. Attorney for the Southern District of Florida, a Confidential Disclosure Statement of all material evidence and information known by Relators and related to the Complaint.

24. This Confidential Disclosure Statement and all referenced documents are protected by the interrelated attorney-client, work-product, common-interest, and joint-prosecutorial privileges/doctrines.

25. Relators are original sources of the information set forth in this Complaint, and have direct and independent knowledge of the allegations set forth herein.

26. All Defendants transact business in this District, and the actions set forth herein occurred in this District. Therefore, this Court has jurisdiction over this case under 28 U.S.C. § 1345, 28 U.S.C. § 1331, and 31 U.S.C. § 3732(a), the last of which provides: "An action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants any one defendant, can be found, resides, transacts business or in which any act proscribed by § 3729 occurred." All Defendants have transacted business in this District.

27. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) for the reasons set forth immediately above.

28. These allegations arise under the qui tam provisions of the federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), as amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21.

29. Under the FCA, this Complaint has been filed *in camera* and under seal.

30. None of the allegations set forth herein are based on a "public disclosure" under 31 U.S.C. §3730(e)(4).

31. Notwithstanding, Relators are "original sources" of the facts set forth herein, as Relators have "direct and independent knowledge" of these allegations.

THE FRAUD

The Orchestrators

32. The principal orchestrators of the fraud were: Diabetic Care Rx, LLC, dba Patient Care America ("PCA"); Riordan, Lewis & Haden, Inc. ("RLH"); Patrick Smith; Matthew Smith; and Thomas Buscemi.

33. The name "Diabetic Care Rx" has been somewhat of a misnomer for years. Initially, with its establishment in December 2005, the company was a mail-order shipper of diabetic supplies. Subsequently, Diabetic Care Rx shifted to shipping sterile-infusion nutrition solutions to dialysis patients nationally, through dialysis centers and directly to home patients, and the company called itself "DCRx Infusion." Infusion of renal nutrition (e.g., amino acids, glucose, lipids) is a covered benefit under Medicare Part D for patients with end-stage renal disease. This is known as intradialytic parenteral nutrition (IDPN) to hemodialysis patients, which is usually treated in dialysis centers, and is known as intraperitoneal nutrition (IPN) to peritoneal dialysis patients, who are usually treated in the home setting.

34. In 2012, RLH purchased PCA for $25 million, became its majority owner, and soon thereafter changed PCA's focus because Medicare had just greatly lowered its reimbursement rates for IDPN and IPN products and services. PCA significantly reduced servicing hemodialysis and peritoneal dialysis patients, and hired a new management team to lead the medical business to profits. In early 2014, defendants Patrick Smith, Matthew Smith, and Thomas Buscemi were hired, and promptly implemented the business strategies that are the gravamen of this complaint.

35. In April 2014, PCA was generating revenue of only approximately $300,000 per month, and losing approximately $350,000 per month. Without conducting any research and development, the Executive Team, under RLH's direction and co-management, quickly turned the company's focus to compounding pain and scar creams.[1] One year later, by April 2015, PCA was generating nearly $30 million per month in revenues, ***a hundred-fold increase***, with a gross profit margin of approximately ninety-eight percent (98%) in its compounding division.

36. At its largest, from approximately March through May 2015, PCA had approximately 150 employees. However, during that time period, PCA bogusly employed employees of the marketing agencies in order to cover up its illicit kickbacks, as explained below. At its smallest, from approximately July through September 2014, PCA had approximately 50 employees.

[1] PCA allocates no money for research and development of its pain creams, scar creams,

37. Patrick Smith was hired in March 2014 as PCA's President and Chief Executive Officer. He promptly replaced the rest of the company's leadership with a new Executive Team, including the individuals named as co-defendants in this *qui tam* Complaint. Patrick Smith oversaw, directed, and managed all aspects of PCA's business. He made and/or approved all of PCA's major decisions. Prior to March 2014 (before the fraud), Robert Funari was PCA's Interim CEO.

38. Matthew Smith was hired by Patrick Smith in April 2014 as PCA's Director of Specialty Pharmacy and Compounding. In September 2014, Patrick Smith promoted him to COO and Vice President of Operations. A registered pharmacist, Matthew Smith was responsible for pharmacy operations and relationships with marketing agencies, including their compensation.

39. Thomas Buscemi was hired by Patrick Smith in April 2014 as PCA's Vice President of Marketing and Sales. Buscemi was responsible for PCA's sales direction and strategies for increasing its market share and revenue. The Director of Compounding Sales, Mark Terrill, reported directly to Buscemi.

40. Each of these three executives had over twenty-five (25) years of experience in health care prior to early 2014. Although Matthew Smith held the specific responsibility of managing the compensation of the marketing agencies, Patrick Smith and Thomas Buscemi were also closely involved in doing so; all three executives considered these kickbacks to be the gateway to high profits.

41. RLH, the private equity group which is the majority owner of PCA, is based in southern California and has over $700 million in committed capital under management, with annual revenues of $25 million to $150 million.

42. On its website, RLH hypes its expertise in the business of health care, especially specialty pharmacy services and outcome data.

43. RLH is not only a huge player in the compound topical pain and wound care cream industry, by majority ownership and co-management of PCA, but is also a major player in the specialty pharmacy industry in general, as part owner of Avella Specialty Pharmacy. Avella operates in eight (8) states in the West and Midwest, serving patients with cancer, organ transplants, AIDS/HIV, infertility, and impaired vision.

44. RLH invests in high-growth, middle-market companies. As its own website makes clear, RLH is not a passive investor. Rather, it collaborates closely and advises on strategic issues. In its website, RLH also vaunts its expertise in the business of health care, including "patient and regulatory compliance, specialty pharmacy services, outcome data, and more."

45. After purchasing the majority of PCA's stock for $25 million in August 2012, RLH conspired with, approved, and bankrolled PCA's specific plan to provide the kickbacks in 2014 and 2015.[2] (RLH did not make this large capital investment in PCA without ensuring that PCA had adopted a new business model that would give RLH a large return on its investment: the kickback scheme at issue).

46. Approximately every two months from July 2012 through July 2015, RLH principals Michel Glouchevitch and Kenneth D. Hubbs met with PCA's Executive Team, Patrick Smith, Matthew Smith, and Thomas Buscemi, as well as the Chairman of RLH's Board of Directors, Robert Funari, to plan, evaluate the progress of, and fine-tune the scheme. These meetings were PCA Board Meetings, and took place at PCA's corporate office, with combinations of Mssrs. Glouchevitch, Hubbs, and Funari traveling to PCA for the meetings. (Funari was the Chairman of PCA's Board from March 2014 through 2015. He was the Chairman of the Board of PCA and its Interim CEO from July 2012 through March 2014.)

47. These RLH principals also engaged in phone calls and e-mails with PCA's Executive Team virtually every week during that time period.

48. From 2013 through 2014, RLH loaned $10 million to PCA. PCA largely used these funds to alleviate the cash-flow problem caused by the delay between the recurring dates that PCA owed the kickbacks to the marketing agencies and the recurring dates that PCA received reimbursements from TRICARE.

49. Near the end of her employment as PCA's Controller and Vice President of Finance, from late 2013 through mid-2014, Cindy Halpern-Cohen complained to RLH, by e-mail, about the kickback scheme. Rather that reversing course, PCA fired her.

TRICARE

50. TRICARE is the component agency of the U.S. Department of Defense that administers

[2] Skyline Global Partners, a minority owner of PCA, has not been named as a Defendant.

and supervises the health care program for certain military personnel and their dependents.

51. TRICARE contracts with a fiscal intermediary (in this case, a pharmacy benefit manager ("PBM"), specifically Express Scripts, that receives, adjudicates, processes and pays health care claims submitted to it by TRICARE beneficiaries or providers.

52. The funds used to pay the TRICARE claims are federal government funds. In addition to Medicare, Medicaid, and TRICARE, the federal government also reimburses for the cost of prescription drugs under several other Government Health Care Programs, including the Railroad Retirement Medicare Program, the Federal Employee Health Benefit Plans, the Veterans Administration, the Indian Health Service and State Legal Immigrant Assistance Grants.

The Anti-Kickback Statute

53. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7(b)(2), was enacted by Congress to prevent improper financial considerations from influencing the amount, type, costs, or selection of health care services financed to any extent by the U.S. Treasury.

54. Kickbacks can take a wide variety of forms, including cash, gifts, supplies, long-term credit arrangements, equipment, and services.

55. It is remuneration, or merely the offering of it, to induce payments by federal programs, that transforms an ordinary, lawful transaction into one that violates the AKS.

56. The AKS broadly defines an "inducement"—i.e., a kickback—to mean "any money, fee, commission, credit, gift, gratuity, thing of value, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor or subcontractor employee, for the purpose of improperly obtaining or rewarding favorable treatment in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52-53.

57. The AKS provides both civil and criminal penalties for offering or paying any remuneration to induce someone to refer patients to or for, or to purchase, lease, or order, any item, service or facility for which payment may be made by a federally funded health care program. 42 U.S.C. §1320a-7(b). This prohibition applies whether the financial benefit is provided directly or indirectly, "in cash or in kind."

58. Compliance with the AKS is a prerequisite for receiving payment from federal health programs.

59. In 2010, Congress amended the AKS when it enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 11-148, 124 Stat. 119 (2010). The amendment makes clearer than ever that claims that are influenced in any way by kickbacks are, by definition, false claims under the FCA. PPACA, 124 Stat. 119, § 6402(g) (amending Section 1128B of the Social Security Act, 42 U.S.C. § 1320a-7(b)(g)).

60. Another PPACA amendment of the AKS clarified that specific intent to violate the AKS, or actual knowledge of a kickback violation, is not required under the FCA. PPACA, § 6402(f)(1).

61. When a compounding pharmacy pays a kickback to a marketing agency, the kickback taints the entire prescription and all related services, regardless of any medical propriety that may exist for its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

62. A kickback is material if it has a natural tendency to influence, or is capable of influencing, the decision-maker to which it is addressed. All of Defendants' kickbacks have been material.

63. The Government is not required to pay for products or services tainted by kickbacks because, under such circumstances, the Government has no assurance that the product or services were provided in the best interests of the patient, instead of the financial interests of the provider and the recipient of the kickback.

The Compound Drugs and Formulary/Order Form

64. PCA is a manufacturer and supplier of compound drugs. A compound drug is a combination of drugs or ingredients prepared by a pharmacist for a patient's individual medical needs.

65. Specifically, PCA manufactured and supplied three (3) principal types of compound topical creams, and one principal type of metabolic capsules/supplements: a pain cream, a scar cream, a wound care cream, and the metabolic capsules supplements. In PCA's own

terminology, these were: (1) "pain management transdermal formulations," (2) "scar formulations," (3) "wound care formulations," and (4) "metabolic supplements."

66. At its height in refilling orders, the compounding group was processing roughly four hundred (400) shipments per week (including each of the 3 prescriptions). This fulfilled orders for roughly 1,550-1,600 compounding patients, of which 95-97% were TRICARE beneficiaries.

67. The "pain management transdermal formulations" were of four types:

A. "P-01 Transdermal" for general pain or inflammation—composed of Tramadol 5%, Flurbiprofen 20%, Cyclobenzaprine 2%, Baclofen 2%, and DMSO 5%;

B. "P-02 Transdermal" for neuropathic or chronic pain—composed of Flurbiprofen 20%, Cyclobenzaprine 2%, Baclofen 2%, Gabapentin 6%, Lidocaine 2.5%, and DMSO 5%;

C. "P-03 Transdermal" for neuropathic pain—composed of Amantadine 8%, Cyclobenzaprine 2%, Baclofen 2%, Diclofenac 3%, Gabapentin 6%, Orphenadrine 5%, Tetracaine 2%, and DMSO 5%; and

D. "P-04 Transdermal" for "combination/pain"—composed of Dextromethorphan 10%, Clonidine 0.2%, Gabapentin 6%, Ibuprofen 10%, Licodaine 2%, and DMSO 5%.

68. If any of the above pain management transdermal formulations were rejected by insurance, one of these two alternative formulas were used:

A. "P-05 Transdermal" for "Therapeutic 1/pain"—composed of Gabapentin 6%, Diclofenac 3%, and Licodaine 2.5%; or

B. "P-06 Transdermal" for "Therapeutic 2/pain"—composed of Ibuprofen 5%, Amantadine 5%, Orphenadrine 5%, Licodaine 5%, Amitriptyline 5%, Guaifenisen 10%, and DMSO 5%.

69. The "scar formulations" were of three types:

A. "SC-01 Transdermal" for "scar/post-op pain"—composed of Fluticasone 1%, Levocetirizine 2%, Prilocaine 3%, Pentoxifylline 0.5%, and Gabapentin 15%;

B. "SC-02 Gel" for "scar"—composed of Tamoxifen Citrte 0.1%, Tranilast 1%, and Caffeine Citrated 0.1%; and

C. "SC-03 Gel" for "surgical or new scar"—composed of Betamethasone Valerate 0.1% and Tranilast 1%.

70. If any of the above "scar formulations" were rejected by insurance, this alternative formula was used: "SC-04" for "scar therapeutic," comprised of: Topiramate 1%, Lidocaine 5%, Hydrocortisone 3%, Pentoxifyline 2%, Diphenhydramine 2%, and Lipoic Acid 5%.

71. The "wound care formulations" were of three types:

A. "WC-01 Gel" for "non-infected wounds," comprised of: Phenytoin 5%, Misoprostol 0.0024%, Aloe Vera 0.2%, and Prilocaine 2%;

B. "WC-02 Gel" for "infected wounds," comprised of: Phenytoin 5%, Misoprostol 0.0024%, Aloe Vera 0.2%, Prilocaine 2%, Levofloxacin 2%, Metronizadole 2%, and Vancomycin 5%; and

C. "WC-03 Cream" for "wound revascularization," comprised of Nifedipine in Lipoderm 4%, 6%, or 8%.

72. There was only one formula for "metabolic supplements": a "general wellness" combination of Parts 1 and 2, with Part 1 consisting of Coenzyme Q-10 100 mg, Lipoic Acid 250 mg, and Vitamin D3 1,000 IU; and Part 2 consisting of Methylcobalamin 10 mg, Pyridoxal 5, Phosphate 70 mg, Resveratrol 100 mg, and Folic Acid 1 mg.

73. PCA listed the above and foregoing formulary options in an order form, which PCA distributed to, and later received from, filled out by, the marketing agencies. The marketing agencies obtained the information from physicians, and filled out the order forms with the physicians.

74. PCA's order form specified that the physician could add or delete any ingredient from these formulations, and contained a list of eleven optional formula additions: Lidocaine 2% (anesthetic), Verapamil 10% (fibrosis/scarring), Acyclovir 5% (anti-viral), Ketoralac 0.6% (acute pain), Baclofen 2% (pain), Nifedipine 2% (tissue perfusion), Amitriptyline 2% (neuropathic), clonidine 0.2% (sympathetic), Imipramine 3% (neorapthic), Ketoprofen 10% (anti-inflammatory), and Pentoxifylline 3% (neuropathic). The order form also contained a blank for an additional ingredient.

75. The formulary/order form was used by all of the marketing agencies. This provided ease of use to the call agents in completing the needed information, and additionally optimized that they secured three (3) prescriptions per patient for each monthly shipment.

76. In 2015, PCA, through Patrick Smith, Matthew Smith, and Thomas Buscemi, modified the order form several times to maximize billing. That is, every time that they determined that they could change an ingredient to increase the price of any of the creams or capsules, they did so. The formulas were never changed in a way that lowered prices. As a result, the formulary/order form was changed various times over an eight-month period to always reflect the ingredients that were paid at a maximum amount ensuring optimal dollars per patient prescription. One optimized pain cream prescription could bring in reimbursement of between $12,000 and just over $20,000, depending on the pharmacy benefits manager ("PBM").

PCA's Revenues and *Modus Operandi*

77. As noted above, in just twelve months, from May 2014 through April 2015, PCA's revenues on prescription-strength, non-sterile, topical pain creams, scar creams, wound care creams, and metabolic supplements/capsules, skyrocketed from approximately $300,000 per month to nearly $30 million per month—***a hundred-fold increase***.

78. The new Executive Team—led by President and CEO, Patrick Smith; Vice President of Operations and CFO, Matthew Smith; and Vice President of Marketing and Sales, Thomas Buscemi—achieved these stunning, sudden revenues by changing PCA's focus from the supply of dialysis infusion therapies to the manufacture and supply of prescription-strength, non-steroidal, topical pain creams and scar creams. For every dollar directly spent on making and shipping these items, the company made approximately ninety-eight percent (98%) gross profit, before the kickbacks. Its net profit on these creams and metabolic capsules, i.e., its profit after the kickbacks, was also huge—in the range of fifty to sixty percent (50-60%).

79. To achieve these bewildering returns, PCA provided enormous kickbacks—between forty (40%) and fifty percent (50%) of the prescriptions' reimbursement, to the following marketing companies that secured prescriptions:

(A) MGTen Marketing Group, Inc.;

(B) The Wink Initiative, Inc.;

(C) M Data and M Data 2;

(D) Pro Pharmx, Inc.;

(E) Rainwater Rose; and

(F) TeleMedTechRx.

80. PCA utilized these marketing agents to find TRICARE patients. The agents asked the patients, in so many words: "Are you in pain? Do you have scars? We can help you. We have doctors who can prescribe this for you. There is no cost to you for our pain creams, scar creams, and wellness capsules."

81. The leaders of the Executive Team—Patrick Smith, Matthew Smith, and Tom Buscemi—were the individuals who formulated and implemented the kickback system.

82. RLH fine-tuned and bankrolled it, as explained further below.

83. At their direction, from August 2014 through July 2015, Alisa Catoggio, Matthew Smith's Executive Assistant, carried out their directive to pay kickbacks to these marketing agencies.

84. The marketing companies utilized physicians to write the prescriptions via telemedicine. That is, each marketing company had doctors in its pocket who would write the prescriptions.

85. Catoggio was also the employee who was most responsible for the weekly activity of billing TRICARE.

86. All claims submissions to TRICARE were done with the "dba" of DCRX; the corporate name was not used.

87. TRICARE utilizes Express Scripts, Inc. as its pharmacy contractor/benefits manager ("PBM"), i.e., its "middleman"-like manager of prescription drug benefits. Therefore, if a TRICARE beneficiary goes to a pharmacy with a prescription, the pharmacy forwards the prescription to Express Scripts. Express Scripts processes and "pays" it, and seeks reimbursement from TRICARE.

88. In the case of PCA, all of its checks came from Express Scripts. However, by causing the writing of prescriptions for the creams and supplement, PCA caused Express Scripts to submit claims to TRICARE.

89. In less than one year's time, from September 2014 through June 2015, these kickbacks totaled approximately $40 million, tainting approximately $87.75 million in claims paid for the compounded creams and capsules.

90. Between January and June 2015, the compounding group had revenues in excess of $77 million, which represents 90.5% of company sales for the first half of 2015.

91. Together with what the compounding group sold in 2014 of an additional $20-21 million, it is estimated that the compounding group adjudicated and received payment by PBMs (almost all through Express Scripts) for approximately $97.5 million for pain creams, scar creams, and wellness capsules.

92. It is also estimated that due to TRICARE being targeted by the PBM of choice by PCA and its marketers, approximately $87.75 million of the compounding revenue could be attributed to Express Scripts/TRICARE reimbursement for their patient beneficiaries that were being targeted.

93. From September 2014 through June 2015, PCA's gross revenues, from reimbursements for its compounded creams and metabolic supplements, totaled $97.5 million.

94. It is conservatively estimated that ninety percent (90%) or greater of this revenue was received from Express Scripts as the PBM for TRICARE (of which 10% were Medicare dual eligible).

95. The balance of the reimbursement revenue was received from commercial insurance PBMs. (While the vast majority of this fraud involves kickback-tainted claims submissions to TRICARE, approximately ten percent (10%) of the Express Scripts/TRICARE claims involved patients who were dual-eligible under both TRICARE and Medicare.) Hence, the $87.75 million figure above.

96. The following chart summarizes PCA's revenues during the time period at issue:

[Please see next page.]

Month	Renal Group	Compounding Group	Company Sales (both groups)
Sept. 2014	$600,000	$2M	$2.6M
Oct. 2014	$725,000	$4M	$4.725M
Nov. 2014	$825,000	$6M	$6.825M
Dec. 2014	$900,000	$8M	$8.9M
Jan. 2015	$1M	$10M	$11M
Feb. 2015	$1.1M	$14M	$15.1M
Mar. 2015	$1.2M	$19.5M	$20.7M
Apr. 2015	$1.3M	$27.7M	$29M
May 2015	$1.4M	$6M	$7.4M
June 2015	$1.5M	$300,000	$1.8M
TOTAL	**$10.55M**	**$97.5M**	**$108.05M**

97. From September 2014 through May 11, 2015, patients frequently called in, complaining that neither they nor their doctors had ever ordered these prescriptions, or that they had received a copay bill but were promised the medication for "free" with no co-pay.

98. One patient even admitted that he or she had been offered $1,000 to take the prescription.

99. These complaints were handled by the billing department that reported to the Reimbursement Services Manager, Relator Ada Lopez.

100. Carmen Greene, Accounting Manager, was responsible for ensuring that the marketing agencies got their Chase Bank cash wire transfers, representing their commissions. Greene reported directly to Patricia Gunn after she was hired in December, but prior to that she reported directly to Patrick Smith.

101. PCA provided the kickbacks to the marketing agencies within thirty (30) days after it received each prescription.

102. This practice caused a major cash-flow problem because PCA did not receive reimbursement from Express Scripts/TRICARE within thirty (30) days. PCA used most of the $10 million loaned by RLH in 2013 and 2014 to alleviate this problem, but it did not solve the problem due to the extremely large amount of kickbacks being paid.

103. PCA instructed the marketing agencies to systematically push all three types of products: the pain creams, scar creams, and wellness capsules. The marketing agencies succeeded in this aggressive campaign. For every TRICARE beneficiary who consented to receive the packet, PCA received $15,000 to $20,000.

104. But PCA and the marketing agents did not stop there. They targeted not only the TRICARE patients themselves, but also their families. For a family of four, for example,

TRICARE reimbursed $60,000 to $80,000 (4 TRICARE family members x $15,000 to $20,000=$60,000 to $80,000).

The Marketing Agencies

105. **MGTen Marketing Group, Inc.** secured more patients/prescriptions, and thus received more kickbacks, than any other marketing company. It is an active Florida Profit Corporation owned and operated by Monty R. Grow, its President. Its principal business address is 5242 Hampton Beach Place, Tampa, FL 33609. Its mailing address is 9832 Brompton Drive, Tampa, FL 33626.

106. From December 2014 through July 2015, MGTen received kickbacks of fifty percent (50%) on the gross profit for every prescription that was filled and reimbursed.

107. **The Wink Initiative, Inc.** is owned and operated by Amy Yap. The company apparently is not registered to do business with the State of Florida. The company is located in greater San Francisco, California.

108. From January through July 2015, The Wink Initiative received kickbacks of forty-five percent (45%) on the gross profit for every prescription that was filled and reimbursed.

109. It is estimated that, collectively, Monty Grow and Amy Yap's marketing agencies, MGTen Marketing Group and The Wink Initiative, were responsible for 75-80% of the prescriptions and revenue being generated in 2015, or approximately $60 million. The kickbacks to MGTen and The Wink Initiative totaled approximately $29 million.

110. **M Data and M Data 2** are located in Atlanta and are owned and operated by Eric Santos. The companies apparently are not registered to do business with the State of Florida.

111. From October 2014 through July 2015, M Data and M Data 2 received kickbacks of forty-five percent (45%) on the gross profit for every prescription that was filled and reimbursed.

112. **Pro Pharmx, Inc.** is owned and operated by Ginger Lay. The company apparently is not registered to do business with the State of Florida. The company is located in Atlanta.

113. From February through July 2015, Pro Pharmx received kickbacks of forty percent (40%) on the gross profit for every prescription that was filled and reimbursed.

114. **Rainwater Rose** was the first call center that PCA used for marketing purposes. It is based in Costa Rica, where it maintains the call center. It is managed by COO Jonathan Lambert.

115. From September 2014 through July 2015, PCA provided Rainwater Rose a forty percent (40%) commission on gross profit for every prescription that was filled and reimbursed. This was done through Alisa Cattogio's acquaintance, marketer Brian Podolak, who provided the introduction to Lambert in Costa Rica.

116. Rainwater Rose targeted patients using information provided to them by Podolak, and used a telemarketing script and facilitating doctor's orders by faxing patient scripts back to the physician for signature, which in turn was faxed back to Rainwater Rose and then to PCA.

117. Commissions of 40% were paid to Rainwater Rose net 30 after receipt of prescription.

118. Additionally, as with all of the marketing agencies, they told patients that they did not have to pay copays as a way of inducing them to get the "free" product that their insurance would cover.

119. Amazingly, Podolak's Linked In page shows the marketing agent's methodologies for providing kickbacks to physicians for pain cream prescriptions. The page, which is addressed to marketing agents that he could compensate, brazenly states:

> Searching for reps who are hungry to earn. Our unique model compensates physicians for their time to collect HIPAA compliant data from their patient base for our pharmacy clients. Physicians earn thousands of dollars a month and takes just moments of one of their office staff's time. You set up the meeting, we will close them, you earn in a big way.
>
> Almost ALL healthcare providers treat patients with some sort of pain on a daily basis. Many providers are even medical surgeons who frequently have the opportunity to write 2 prescriptions for a patient – one being for pain and another to help with scarring. Ask any physician how many of their patients are 100% pain free and they will tell you none of them are entirely pain free.
>
> Responsibilities:
>
> -Leverage existing physician relationships to market the products…
>
> Requirements:….
>
> *Already marketing transdermal pain, wound, scar or other compound therapies? If so, we'd like to speak with you if you are experiencing any of the following:
> * You are getting paid only minimal dollars per script.
> * Not able to offer your physicians a professional services agreement.
> * You are not pleased with the service your compounding pharmacy is providing to you or your providers and patients.

Compensation:

You should be able to make a six figure income even at a part time status if you have the relationships experience and drive. Reps take home $80,000 per year on the low end…Top reps take home $50K + per month.

Let's talk today.

120. **TeleMedTechRx** is based in California and is owned and operated by Steven Miller.

121. From November 2014 through July 2015, PCA provided the company kickbacks of forty-five percent (45%) on the gross profit for every prescription that was filled.

122. On Steve Miller's Linked In page, the marketing agent boasts that "We Buy Leads." It is clear that he is talking about leads for physicians who will write prescriptions "within THE COMPOUND TOPICAL PAIN CREAM VERTICAL [market]." (all caps in original) He also states that "[w]e can guarantee you will make more with us than you currently are on backend structured deals." *Id.*

123. TeleMedTechRx also had a unique system to avert the patient paying the copayment—basically covering the copay 50% itself, and PCA paying the other 50% of the copay.

124. This was done by PCA paying a third party company named Pfarn 50% of the copays, and TeleMedTechRx doing the same. (Pfarn was in alliance or owned by TeleMedTechRx.) Pfarn then issued a money order to PCA for the entire copay amount on behalf of the patient(s). Relator Lopez was responsible for the exchange with Pfarn of monies.

The Attempted Cover-Up Through Sham Employment of the Marketers

125. Once the kickback scheme became hugely profitable in early 2015, RLH became more apprehensive and urged PCA to make it "legal."

126. In turn, PCA made all the contracted marketing agencies "employees" of PCA. A human resources consultant was retained for this purpose: Phil Lockwood, who had worked with Patrick Smith previously.

127. PCA promptly hired seventy-nine (79) of the marketers—most of whom worked for MGTen, MData and MData2. This virtually doubled PCA's employee count overnight.

128. To facilitate this, PCA increased the commissions/kickbacks to 50% with some of the marketing agencies.

129. Most of these "new" employees were not happy with the new arrangement due to having taxes being withheld from their "paychecks."

130. Human resources got them on board quickly, to make them appear like "bona fide" employees under the Anti-Kickback Statute's safe harbors. Virtually all marketing agency personnel were on board as W-2 employees by the end of March 2015.

131. These 79 new "employees" were employees by classification only. Although PCA's human resources department sent them "new hire" packages, PCA continued to exert little or no control over them. They did not begin working in PCA's offices; they stayed in their own marketing companies, with continued supervision by their prior, non-PCA supervisors. They did not begin taking instructions from PCA and reporting to PCA; they continued to take instructions from, and continued to report to, the supervisors in their own marketing agencies. PCA did not set or regulate their hours, or cover their expenses. PCA did not provide them computers, phones, or other equipment. They did not receive company email accounts. They were not included on company announcements and were not provided company business cards.

132. Last but not least, a few of these employees were making millions of dollars—specifically Monty Grow, Amy Yap, and Eric Santos. Of course, true employees rarely make that high amount of compensation, particularly as marketing agents.

133. It was evident to everyone internally that these were not legitimate employees, but only employees in name for bogus "safe harbor" reasons.

134. Although PCA began paying the new employees, PCA abruptly stopped doing so and fired them all, only two months after PCA "hired" them.

Waiver of Patient Co-Payments

135. Defendants, through Patrick Smith, Matthew Smith, and Thomas Buscemi, routinely, fraudulently waived the required co-payments of all, or virtually all, TRICARE beneficiaries.

136. Although the telemarketing agencies representing PCA routinely told patients that they would not have to pay anything out of pocket for the creams and capsules discussed above, PCA routinely billed patients for co-payments. When PCA ultimately waived copayments for virtually all patients, however, it never required that patients show an inability to pay.

137. RLH, through principals Michel Glouchevitch and Kenneth D. Hubbs, and the Chairman of PCA's Board of Directors, Robert Funari, agreed to and ratified this practice.

COUNT 1:
FEDERAL CIVIL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1), AS AMENDED BY FERA

138. Relators reallege the allegations of paragraphs 1 through 137 as if fully set forth herein.

139. This is a civil action by Relators, acting on behalf of the Government, against all Defendants.

140. All Defendants have knowingly submitted false claims for payment, or caused false claims for payment to be submitted, to officials of the Government, including TRICARE, in violation of **31 U.S.C. § 3729(a)(1)**.

141. As a direct and proximate result of Defendants' conduct, the Government has suffered actual damages, having made payments and/or reimbursements.

142. All Defendants, by and through one or more officers, agents, or employees, knowingly made, used, or caused to be presented, to an officer of the Government, false or fraudulent claims for payment, reimbursement or approval.

143. All Defendants, by and through one or more officers, agents, or employees, authorized these agents to take the actions set forth above.

144. WHEREFORE Relators, on behalf of themselves and the Government, pray that after due proceedings:

- This Court enter judgment against Diabetic Care Rx, LLC, dba Patient Care America; Riordan, Lewis & Haden, Inc.; Patrick Smith; Matthew Smith; and Thomas Buscemi; in an amount equal to three times the amount of damages the Government has sustained, plus a civil penalty of $5,500.00 to $11,000.00 for each and every false claim that was presented to the Government;
- This Court grant permanent injunctive relief to prevent any recurrence of violations of the FCA, ordering all Defendants to cease and desist from violating the FCA;
- The Government and Relators be awarded all reasonable attorneys' fees, costs, expenses, pre-judgment interest, and post-judgment interest;

The Government and Relators recover any and all relief, both at law and in equity, to which they may reasonably be entitled; and

- The Government and Relators each be awarded the maximum amount and receive all of the rights and benefits allowed by the FCA and the FERA.

COUNT 2:
FEDERAL CIVIL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(2), AS AMENDED BY FERA

145. Relators reallege the allegations of paragraphs 1 through 137 as if fully set forth herein.

146. This is a civil action by Relators, acting on behalf of the Government, against all Defendants.

147. All Defendants, by and through one or more officers, agents, and/or employees, knowingly made, used or caused to be made or used, false records or statements, to get false or fraudulent claims paid, reimbursed, or approved, in violation of **31 U.S.C. § 3729(a)(2)**.

148. As a direct and proximate result of Defendants' conduct, the Government has suffered actual damages, having made payments and/or reimbursements.

149. All Defendants, by and through one or more officers, agents, or employees, knowingly made, used, or caused to be presented, to an officer of the Government, false or fraudulent claims for payment, reimbursement or approval.

150. All Defendants, by and through one or more officers, agents, or employees, authorized these agents to take the actions set forth above.

151. WHEREFORE Relators, on behalf of themselves and the Government, pray that after due proceedings:

- This Court enter judgment against Diabetic Care Rx, LLC, dba Patient Care America; Riordan, Lewis & Haden, Inc.; Patrick Smith; Matthew Smith; and Thomas Buscemi; in an amount equal to three times the amount of damages the Government has sustained, plus a civil penalty of $5,500.00 to $11,000.00 for each and every false claim that was presented to the Government;
- This Court grant permanent injunctive relief to prevent any recurrence of

violations of the FCA, ordering all Defendants to cease and desist from violating the FCA;

- The Government and Relators be awarded all reasonable attorneys' fees, costs, expenses, pre-judgment interest, and post-judgment interest;

The Government and Relators recover any and all relief, both at law and in equity, to which they may reasonably be entitled; and

- The Government and Relators each be awarded the maximum amount and receive all of the rights and benefits allowed by the FCA and the FERA.

COUNT 3:
FEDERAL CIVIL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(3), AS AMENDED BY FERA

152. Relators reallege the allegations of paragraphs 1 through 137 as if fully set forth herein.

153. This is a civil action by Relators, acting on behalf of the Government, against all Defendants.

154. All Defendants, by and through one or more officers, agents, and/or employees, "conspired to defraud the Government by getting…false or fraudulent claims allowed or paid," in violation of **31 U.S.C. § 3729(a)(3)**.

155. As a direct and proximate result of Defendants' conduct, the Government has suffered actual damages, having made payments and/or reimbursements.

156. All Defendants, by and through one or more officers, agents, or employees, knowingly made, used, or caused to be presented, to an officer of the Government, false or fraudulent claims for payment, reimbursement or approval.

157. All Defendants, by and through one or more officers, agents, or employees, authorized these agents to take the actions set forth above.

158. WHEREFORE Relators, on behalf of themselves and the Government, pray that after due proceedings:

- This Court enter judgment against Diabetic Care Rx, LLC, dba Patient Care America; Riordan, Lewis & Haden, Inc.; Patrick Smith; Matthew Smith; and Thomas Buscemi; in an amount equal to three times the amount of damages the

Government has sustained, plus a civil penalty of $5,500.00 to $11,000.00 for each and every false claim that was presented to the Government;

- This Court grant permanent injunctive relief to prevent any recurrence of violations of the FCA, ordering all Defendants to cease and desist from violating the FCA;
- The Government and Relators be awarded all reasonable attorneys' fees, costs, expenses, pre-judgment interest, and post-judgment interest;

The Government and Relators recover any and all relief, both at law and in equity, to which they may reasonably be entitled; and

- The Government and Relators each be awarded the maximum amount and receive all of the rights and benefits allowed by the FCA and the FERA.

JURY REQUEST

159. Relators request a jury trial for all issues so triable.

DATED MARCH 4, 2016

Respectfully submitted:

s/ Steven F. Grover

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