

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

UNITED STATES OF AMERICA,
ex rel., JENNIFER SILVA and
JESSICA ROBERTSON

Plaintiff,

v.

Case No. 8:15-cv-00444-T-33TGW

Z STAT MEDICAL, LLC d/b/a OLDSMAR
PHARMACY,
STAT DIRECT, LLC, and
LARRY 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 Z Stat Medical, LLC d/b/a Oldsmar Pharmacy; Stat Direct, LLC; and Larry 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, the pharmacy paid kickbacks to marketers to target military members and their families for prescriptions for compounded medicated pain creams and scar creams, regardless of need.

2. As set forth below, as part of this scheme, from September 2014 to February 2015, Defendant Larry Smith via Defendant Z Stat Medical LLC d/b/a/ Oldsmar Pharmacy (“Oldsmar Pharmacy”) knowingly submitted and/or caused the submission of claims to TRICARE for reimbursement for compounded drugs that were false or fraudulent because they were tainted by kickbacks to marketers. Specifically, Defendants shared a percentage of the profits – the kickbacks – with the marketing companies that generated referrals. The marketers with whom Larry Smith entered into kickback arrangements included Centurion Compounding, Inc. and Scott Roix (via his companies Health Saving Solutions and Vici Marketing). In addition, the Defendants knew or should have known based on the quantity of prescriptions approved and their own control over the type of prescriptions issued that the prescriptions underlying the claims for reimbursement did not arise from valid prescriber-patient relationships, rendering the claims false.

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 Jennifer Silva and Jessica Robertson are former employees of

companies owned and/or operated by Larry Smith who allege that the Defendants violated the False Claims Act by submitting false claims to TRICARE.

5. Defendant Z-Stat Medical LLC d/b/a Oldsmar Pharmacy has a principal address of 34911 US Hwy 19 N Palm Harbor, FL 34684. Larry Smith was the President, and the company was registered as being managed by Stat Direct LLC (“Stat Direct”). Oldsmar Pharmacy advertised itself as the specialty compounding division of Stat Direct.

6. Defendant Stat Direct is an active Florida corporation with a principal address of 8222 118th Ave N Largo, FL 33773 and is managed by Larry Smith.

7. Defendant Larry Smith resides in Pinellas Park, FL.

III. JURISDICTION AND VENUE

8. 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.

9. 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 Middle District of Florida.

10. Venue is proper in the Middle 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

11. 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. at § 3729(b)(1). No proof of specific intent to defraud is required. Id.

12. 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 or 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.

13. 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).

14. The AKS contains several exceptions in which the prohibition 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).

15. As set forth in more detail below, Defendants knowingly and willfully paid remuneration to marketers to obtain referrals for compound drug prescriptions reimbursed by TRICARE.

16. By providing kickbacks 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.

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

18. 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.

19. 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.

20. Each compounded drug claim submitted by a pharmacy for reimbursement from TRICARE generally includes specific representations about the date of service, the patient on whose behalf payment is being sought, the provider who prescribed the medication, and the individual ingredients contained in the compounded drug.

21. 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.

22. 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.

23. At al 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.

24. 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. at § 199.9(c)(12). Abusive situations include the routine waiver of patient copayments. Id. at § 199.9(b)(1).

25. 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).

26. To receive reimbursement from TRICARE for compounded drugs, a pharmacy must enter into a Provider Agreement with ESI, TRICARE's pharmacy benefits manager.

27. 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.

28. Oldsmar Pharmacy contracted with two Pharmacy Services Administration Organizations (PSAOs), who in turn contracted with ESI as the agent of pharmacies such as Oldsmar Pharmacy.

29. The PSAOs, on behalf of Oldsmar Pharmacy and others, executed Provider Agreements with ESI in which Oldsmar Pharmacy 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....” and
- b. act “in accordance with the professional standards prevailing in the community at the time such services are rendered.”

30. In the Provider Agreements, ESI expressly reserved the right to reverse any claim that Oldsmar Pharmacy or any pharmacy submitted for a prescription when that pharmacy “failed to...verify that the prescription was issued in accordance with applicable laws, rules and regulations.”

31. In addition, Oldsmar Pharmacy promised through the 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 February 28, 2015 required Oldsmar Pharmacy 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].”

33. The ESI Provider Manuals in effect during the period from September 1, 2014 to February 28, 2015 also required Oldsmar Pharmacy 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 Oldsmar Pharmacy, then Oldsmar Pharmacy “may be subject to immediate termination” from ESI’s provider network.

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. Larry Smith’s kickback arrangement with Centurion marketing company

37. Oldsmar Pharmacy is a compounding pharmacy that was owned during the relevant time by Larry Smith. In November 2014, Oldsmar Pharmacy entered into a kickback arrangement with Centurion Compounding, Inc. (“Centurion”) under which Oldsmar Pharmacy and Centurion agreed to split the profits of TRICARE prescriptions in exchange for referrals.

38. Six months earlier, in May 2014, Centurion first sought an agreement with Oldsmar Pharmacy to generate and send prescriptions to Oldsmar Pharmacy in exchange

for a percentage of the revenues from the prescriptions. Smith offered Centurion 25% of Oldsmar Pharmacy's revenue from the prescriptions, which Centurion rejected.

39. Instead, Centurion entered into a marketing agreement with the owners of LifeCare Pharmacy. Centurion engaged sales representatives as independent contractors to market expensive compounded medications, specifically creams for pain and scars, among others, to beneficiaries of healthcare plans, especially TRICARE. Between May 2014 and November 2014, the co-owners of Centurion – Frank V. Monte and Kimberly S. Anderson – directed the patients that Centurion sales representatives had recruited and the physicians in their network to send all of their compounded cream prescriptions to Centurion, which then transmitted them to LifeCare Pharmacy to fill. LifeCare Pharmacy paid Centurion an illegal kickback of approximately 50% of each claim paid by TRICARE.

40. During this same period, the owners of LifeCare Pharmacy entered into an agreement with the principals of Centurion to pay illegal kickbacks to Dr. Anthony Baldizzi. LifeCare Pharmacy and Centurion agreed to pay Dr. Baldizzi 10 percent of the profit for each paid claim resulting from a prescription for compounded cream written for his patients and filled at LifeCare Pharmacy.

41. In November 2014, after LifeCare Pharmacy started withholding payment from Centurion as the result of an audit by a private insurer, Centurion took its business to Oldsmar Pharmacy. Centurion continued to engage sales representatives as independent contractors to market expensive compounded medications, specifically creams for pain and scars, among others, to beneficiaries of healthcare plans, especially

TRICARE. Centurion continued to direct the patients that Centurion sales representatives had recruited and the physicians in their network to send all of their compounded cream prescriptions to Centurion, which then transmitted them to Oldsmar Pharmacy to fill.

42. Smith and others employees of Oldsmar Pharmacy negotiated with Anderson, co-owner of Centurion, the commission that Oldsmar Pharmacy would pay to Centurion per prescription that Centurion referred to Oldsmar Pharmacy.

43. The final arrangement, documented in a mid-December 2014 email, involved taking “15% of [sic] the top, so we split 85 percent profits 50/50 as discussed.”

44. The companies maintained spreadsheets of all of the prescriptions generated by Centurion, the amounts received by Oldsmar Pharmacy for claims that the pharmacy submitted to the patients’ insurance for reimbursement, and the amounts owed in commission, thereby documenting the kickback arrangement. Centurion referred to the spreadsheets as commission reports, which Oldsmar Pharmacy would audit. The commission reports included prescriptions submitted to both private insurance and federal health care programs.

45. For example, the commission report for December 1, 2014 through December 15, 2014 identified over \$9,700,000 received by Oldsmar Pharmacy and over \$3,500,000 in commissions owed to Centurion.

46. The commission reports showed that the vast majority of prescriptions from federal beneficiaries were submitted to TRICARE.

47. In addition to the kickback arrangement with Centurion, Oldsmar

Pharmacy also regularly waived co-pays for the TRICARE prescriptions (and others), thereby inducing additional prescriptions.

48. Also starting in November 2014, Oldsmar Pharmacy and Centurion sought the assistance of attorneys to try to create a legally permissible arrangement whereby the relationship between Centurion and Oldsmar Pharmacy could continue and the individual marketers could be compensated on a commission basis. The parties were never able to reach such a written arrangement, but the kickback arrangement continued.

49. From November 2014 to February 2015, Oldsmar Pharmacy submitted approximately 4,000 claims to TRICARE for compounded prescriptions that Centurion arranged for Oldsmar to fill in exchange for commissions on each prescription.

TRICARE paid approximately \$18,000,000 for those prescriptions.

50. During that time, Oldsmar Pharmacy paid \$6,147,305.89 to Centurion as commissions. Centurion then disbursed to its independent contractor sales representatives their share of the commissions for the prescriptions they generated.

Oldsmar Pharmacy made four payments to Centurion:

Date	Payment
December 1, 2014	\$1,500,000
December 15, 2014	\$500,000
January 2, 2015	\$1,500,000
January 20, 2015	\$2,647,305.89
Total	\$6,147,305.89

51. Smith, President of Oldsmar Pharmacy, knew that the money paid to Centurion was used to pay commissions to the marketers, who were not employees of Oldsmar Pharmacy or Centurion.

52. The only work the Centurion marketers performed in exchange for the commissions was to generate prescriptions that went to Oldsmar Pharmacy.

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

54. The United States executed a search warrant on Oldsmar Pharmacy and others on February 10, 2015.

55. On February 13, 2015, DHA sent a letter to Smith suspending payments for present and future claims from Oldsmar Pharmacy.

56. The two owners of LifeCare and Dr. Baldizzi have entered guilty pleas. Monte and Anderson have been indicted for one count of conspiracy, five counts of paying healthcare kickbacks, one count of conspiracy to commit money laundering, and three counts of illegal monetary transactions.

B. Larry Smith's kickback arrangement with Scott Roix

57. Larry Smith and Scott Roix also entered into an agreement for Scott Roix's companies, including Health Savings Solutions, to provide prescriptions to Oldsmar Pharmacy.

58. Companies associated with Roix, including Health Saving Solutions, would publish online advertisements offering free consultations for pain creams.

59. Customers would call the number listed in the advertisement and speak with telemarketers at Vici Marketing, a call center company owned by Roix.

60. Customers who met certain requirements, such as having insurance that would pay for compounded medications, would be put in contact with a telemedicine company, and the doctor would issue a prescription for a compounded medication without seeing the patient. The resulting prescription would go to one of Roix's companies, who would then send the prescription to Oldsmar Pharmacy to fill.

61. When customers had Medicare or Medicaid, however, the telemarketers would, consistent with their script, not connect those potential customers with the telemedicine company because Medicare and Medicaid would not reimburse for those prescriptions.

62. Oldsmar Pharmacy would submit a claim for reimbursement to private payors and federal health care programs and then include the amount of the reimbursement in the next commission payment to Health Saving Solutions.

63. The amount paid by Oldsmar Pharmacy to Health Saving Solutions was approximately 41 percent of the revenue for each prescription.

64. Smith and Roix entered into an agreement dated September 1, 2014. Smith signed on behalf of his company Direct Telemedicine Resources, Inc. (which provides management and consulting services for businesses, including for Oldsmar Pharmacy) and Roix signed on behalf of Health Saving Solutions.

65. As evidenced by the fact that the parties did not bother to satisfy significant requirements of the contract, the agreement was a sham designed to make it appear that there was a legitimate business relationship and conceal the kickback arrangement.

66. As part of the agreement, Smith's company agreed to compensate Roix's company in the amount of \$5.5 million for services performed from September 1, 2014 to February 28, 2015. Contrary to the actual arrangement, the agreement states that "compensation is not and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated for or with respect to a pharmacy or between the parties for which payment may be made in whole or in part under Medicare or any federal or state health care program or under any other third party payor." In fact, Oldsmar Pharmacy's payments to Health Saving Solutions were based on the value of business generated by Oldsmar Pharmacy.

67. The agreement provides that Health Saving Solutions shall comply with all applicable state and federal healthcare laws, including anti-kickback laws. Health Savings Solution and Roix did not.

68. The agreement bars Health Saving Solutions from soliciting "any federal health care program beneficiaries, such as Medicare, Medicaid, or Tricare beneficiaries, on behalf of a pharmacy." In fact, Health Saving Solutions and/or related entities specifically solicited TRICARE beneficiaries, but not beneficiaries of other federal healthcare programs.

69. The agreement required Health Saving Solutions to provide monthly reports "detailing its marketing and promotion efforts, including venues chosen, contacts that were made, and meetings that were held." In fact, Health Saving Solutions never provided monthly reports to Oldsmar Pharmacy.

70. The parties to the agreement used a spreadsheet to keep track of

prescriptions, the amount received for each prescription, and the commission owed to Health Saving Solutions per prescription.

71. From September 2014 to February 2015, Oldsmar Pharmacy submitted approximately 700 prescriptions to TRICARE for compounded prescriptions that Health Saving Solutions arranged for Oldsmar to fill in exchange for a commission on each prescription. TRICARE paid approximately \$3.4 million for the prescriptions.

72. Oldsmar Pharmacy made the following payments to Health Saving Solutions:

Date	Payment
October 16, 2014	\$5,752.90
October 31, 2014	\$9,214.36
November 17, 2014	\$71,977.18
December 1, 2014	\$201,305.50
December 16, 2014	\$293,212.65
January 2, 2015	\$270,600.23
January 20, 2015	\$452,067.16
February 2, 2015	\$890,718.99
March 13, 2015	\$1,205,151.03
March 23, 2015	\$1,000,000.00
April 17, 2015	\$1,000,000.00
Total	\$5,500,000.00

73. The last three payments were made after the Oldsmar Pharmacy search warrant was executed.

74. The only work Health Saving Solutions performed in exchange for the commissions was to generate reimbursable prescriptions for Oldsmar Pharmacy to fill.

75. Consistent with their status as independent contractors, Health Saving Solutions and Vici Marketing were not given specific work assignments by Oldsmar

Pharmacy. The pharmacy did not control how the companies generated the prescriptions that were sent to the pharmacy and did not supervise the marketers.

C. Prescriptions were not based on valid practitioner-patient relationships.

76. Oldsmar Pharmacy was a compounding pharmacy. According to Oldsmar Pharmacy's marketing materials, "We know each person is unique, and that's why we customize every prescription to fit each individual's need," and "Our compounding professionals can prepare unique dosage forms containing the best dose of medication for each individual."

77. In reality, Oldsmar Pharmacy, with the assistance of the marketing companies, rather than the prescribing doctors, designed the compounds to maximize profits on each prescription.

78. As noted above, Centurion engaged sales representatives to market compounded medications, specifically creams for pain and scars, among others, to beneficiaries of healthcare plans, especially TRICARE.

79. Almost all of the patients who received compounded medication received pain cream or scar cream that had the highest rates of reimbursement.

80. Oldsmar Pharmacy designed prescription pads that Centurion and the sales representatives provided to patients to give to doctors that included compound medications that would be reimbursed.

81. Similarly, Health Saving Solutions provided the list of compound medications that telemedicine doctors were going to offer to patients who responded to the advertisements. In practice, those patients received one of just three formulas.

82. Smith would discuss with Centurion the prescriptions that they should encourage doctors to prescribe because of the amount that insurance paid for them. Smith also provided advice to Centurion on how to encourage doctors to complete the prescriptions pads to increase the likelihood and the amount of reimbursement.

83. For example, the doctors were encouraged to sign prescriptions with unlimited refills in order to maximize revenue for Oldsmar Pharmacy and the marketers.

84. Similarly, patients who spoke with telemarketers at Vici Marketing were also encouraged to agree to automatic refills before speaking with a medical professional or even learning what they would be prescribed.

85. Smith was also aware that Centurion would target doctors with TRICARE patients, including those in close proximity to MacDill Air Force Base.

86. In addition, Oldsmar Pharmacy sometimes waived co-payments for prescriptions, in violation of TRICARE regulations and its own policies, in order to encourage patients to continue accepting medications, including when patients expressed they did not want or need them.

87. The Centurion commission reports also documented the large quantity of prescriptions from particular providers, including from Dr. Anthony Baldizzi.

88. In fact, the number of prescriptions Centurion generated overwhelmed Oldsmar Pharmacy, so Centurion sent some of the sales representatives to Oldsmar Pharmacy to help process the prescriptions in order to receive payments from TRICARE and private insurance companies.

89. Employees of Oldsmar Pharmacy were aware that patients would

sometimes call and say they never asked for the prescriptions and did not see the doctors.

90. Oldsmar Pharmacy and the marketing companies' collusion in arranging for TRICARE patients to order the prescriptions that resulted in the most profits for the pharmacy and marketers improperly influenced the selection of ingredients in compound formulas.

91. Oldsmar Pharmacy knew or should have known that many of the prescriptions received from its marketing partners were not based in a valid patient-practitioner relationship.

D. Defendants were aware of the prohibitions of the Anti-Kickback Statute.

92. Having been in the health care industry as the owner of a pharmacy, Smith was familiar with laws and regulations governing billing to federal health care programs, including the AKS.

93. In fact, Smith had conducted his own independent research into the anti-kickback laws. Specifically, Smith was aware that no pharmacy could pay a commission per prescription to any marketing firm in connection with government funded insurance claims because it was illegal. Smith also understood this to be a norm in the pharmacy industry.

94. As noted above, Smith and Roix entered into an agreement that explicitly barred receipt of money connected to federal healthcare claims and required Roix's company to comply with federal anti-kickback laws.

E. Defendants' conduct was material.

95. 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 reimbursed by TRICARE.

96. Pursuant to the Provider Agreements with ESI, Oldsmar Pharmacy falsely promised that it would comply with all applicable fraud, waste and abuse laws, which include the AKS and the FCA. Oldsmar Pharmacy'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.

97. Defendants knew that compliance with the AKS was a material requirement for receiving TRICARE reimbursement.

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

99. No person or entity on Oldsmar Pharmacy's behalf sought approval from DHA/TRICARE for Oldsmar Pharmacy's payments to third-party marketers of a percentage of Oldsmar Pharmacy's revenue on TRICARE reimbursements for compounded drugs.

F. The United States suffered damages.

100. TRICARE paid approximately \$18 million for prescriptions illegally induced by kickbacks to Oldsmar Pharmacy in connection with the scheme with Centurion from November 2014 until the February 2015 search warrant. In this time period, Oldsmar Pharmacy submitted approximately 4,000 such claims to TRICARE.

101. TRICARE paid approximately \$3.4 million for prescriptions illegally

induced by kickbacks to Health Saving Solutions in connection with the scheme with Roix from September 2014 until February 2015. In this time period, Oldsmar Pharmacy submitted approximately 700 such claims to TRICARE.

102. Only after the United States executed a search warrant that notified Oldsmar Pharmacy that the Government was aware of its improper conduct, Oldsmar Pharmacy paid more than \$19 million to ESI, which included all amounts received for claims submitted in connection with Centurion. Oldsmar Pharmacy also reversed approximately \$40 million in pending claims before they could be paid by TRICARE.

G. Representative claims.

103. L.M. was a patient referred to Oldsmar Pharmacy by Centurion. Oldsmar Pharmacy filled prescription No. 524128, which was signed by Dr. Victor Cruz, and submitted it to TRICARE on December 26, 2014, who paid Oldsmar Pharmacy \$8,576.59 on January 21, 2015. Oldsmar Pharmacy did not collect a copayment from L.M.

104. B.H. was a patient referred to Oldsmar Pharmacy by Centurion. Oldsmar Pharmacy filled prescription No. 538858, which was signed by Dr. Anthony Baldizzi, and submitted it to TRICARE on January 5, 2015, who paid Oldsmar Pharmacy \$6,343.91 on January 21, 2015. Oldsmar Pharmacy did not collect a copayment from B.H.

105. R.G. was a patient referred to Oldsmar Pharmacy by Health Saving Solutions or a related entity. Oldsmar Pharmacy filled prescription 530742, which was signed by Dr. Vinson DiSanto, and submitted it to TRICARE on December 19, 2014,

who paid Oldsmar Pharmacy \$8,677.17 on January 7, 2015.

FIRST CAUSE OF ACTION

(False or Fraudulent Claims)

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

106. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 108.

107. 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/or did not arise from a valid practitioner-patient relationship.

108. 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)

109. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 108.

110. This is a claim by the United States for the recovery of monies that

TRICARE paid to Oldsmar Pharmacy by mistake for compounded drugs that were tainted by kickbacks to marketers and patients and/or did not arise from a valid practitioner-patient relationship.

111. As a consequence of the conduct and the acts set forth above, Oldsmar Pharmacy 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 by the Defendants.

THIRD CAUSE OF ACTION

(Unjust Enrichment)

112. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 108.

113. This is a claim by the United States for recovery of monies by which the Defendants have been unjustly enriched.

114. By virtue of the conduct and the acts described above, Defendants were 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 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 Oldsmar Pharmacy, and illegally retained by the Defendants, 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 amount the Defendants were unjustly enriched, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.
4. All other and further relief as the Court may deem just and proper.

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

Respectfully submitted, this 18th day of October, 2018.

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