

**UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION**

UNITED STATES OF AMERICA ex
rel. ELIZABETH PETERS YOUNG,

Plaintiff-Relator,

v.

BTW SOLUTIONS, LLC, INFINITY
COMPOUNDING SOLUTIONS, LLC
d/b/a INFINITY CARE SOLUTIONS,
DANIEL A. NICHOLSON,
PERIMETER ORTHOPAEDICS, P.C.,
FEROZE YUSUFJI, ATLANTA
ORTHOPEDIC CENTER, P.C., JOHN
DORRIS, DAVID BACASTOW,
DAVID RYAN, LOGAN FIELDS,
ATHENS BONE & JOINT, P.C.,
GARY A. LEVENGOOD, SAADIQ
EL-AMIN, III, CHRISTOPHER R.
SELLARS, SPORTS MEDICINE
SOUTH, LLC, THOMAS MYERS,
and MYERS SPORTS MEDICINE
AND ORTHOPAEDIC CENTER,
L.L.C.,

Defendants.

FILED UNDER SEAL
Pursuant to 31 U.S.C. § 3730

Civil Action No. _____

Jury Trial Demand

False Claims Act Complaint

INTRODUCTION

1. Relator Elizabeth Peters Young (the “Relator”) brings this *qui tam* action on her own behalf and on behalf of the United States of America to recover civil damages and penalties under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, the Federal Employees’ Compensation Act, 5 U.S.C. § 8108 *et seq.* (“FECA”), the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7a *et seq.* (“AKS”), and the Physician Self-Referral Law a/k/a the Stark Law, 42 U.S.C. § 1395nn *et seq.* Relator brings this action against Defendants BTW Solutions, LLC (“BTW”), Infinity Compounding Solutions, LLC d/b/a Infinity Care Solutions (“Infinity”), and against Daniel A. Nicholson, Perimeter Orthopaedics, P.C., Feroze Yusufji, Atlanta Orthopedic Center, P.C., John Dorris, David Bacastow, David Ryan, Logan Fields, Athens Bone & Joint, P.C., Gary A. Levengood, Saadiq El-Amin, III, Christopher R. Sellars, Sports Medicine South, LLC, Thomas Myers, and Myers Sports Medicine and Orthopaedic Center, L.L.C. (collectively, the “Physician Defendants”).

2. Relator’s allegations concern illegal compensation arrangements and self-referrals between BTW Solutions, LLC and Infinity Compounding Solutions, LLC d/b/a Infinity Care Solutions (collectively, “BTW-I”), on the one hand, and the Physician Defendants, on the other.

3. In summary, beginning at a date unknown to Relator but lasting in any event for several years, BTW-I knowingly, willfully, and intentionally offered to provide topical analgesic and anesthetic creams and patches, including medicines marketed as Lidopro, Medrox, and Terocin, to the Physician Defendants at cost – a price far lower than their fair market value – as part of a scheme to earn future referrals and kickbacks in the form of an elevated, well-above-market payment for management and claims-processing services. These services were priced at fifty percent of the reimbursement BTW obtained (less the actual cost of the creams and patches) for claims submitted through the Office of Workmen’s Compensation Programs, a division of the United States Department of Labor (“USDOL”). The scheme allows physicians to provide creams and patches through a point-of-care dispensary program, which also provides for unmediated payments to the Physician Defendants from BTW-I in exchange for prescription referrals.

4. BTW-I offered these services and this sub-market pricing for its medical products so long as the Defendant Physicians only purchased these products from BTW-I. Contracts drafted by BTW-I provide for the Physician Defendants to purchase, prescribe, and dispense BTW-I products to their patients enrolled in workman’s compensation programs eligible for reimbursement through an Office of Workers’ Compensation program (“eligible program”). In return,

BTW-I offered (a) topical creams and patches at cost, far below their fair market value, and (b) billing, collections, “management,” and claims-processing services.

5. As payment, BTW-I demands of the Physician Defendants an equal share of net payments received from USDOL for the claims BTW-I processed, after accounting for the cost of the product dispensed. This division of proceeds is not customary in the industry and is based on the number of referrals of prescriptions made by Physician Defendants, and thus constitutes remuneration within the means of the Federal Anti-Kickback Statute and the Stark Law.

6. By knowingly and willfully offering and providing remuneration to the Physician Defendants in exchange for exclusive referrals for prescriptions for eligible patients, BTW-I violated the Federal Anti-Kickback Statute. By the same token, by knowingly and willfully entering arrangements to receive remuneration in exchange for committing to deliver and actually delivering exclusive referrals for prescriptions for eligible patients, each of the Physician Defendants violated the Federal Anti-Kickback Statute.

7. By submitting claims for prescriptions for eligible patients to USDOL, while knowing those claims were referred from a physician or physicians’ group practice with which it enjoyed a compensation arrangement, BTW-I violated the Stark Law. By the same token, by referring prescriptions for medical products to a

provider with which it enjoyed a compensation arrangement, each of the Physician Defendants violated the Stark Law.

8. By presenting claims for payment to USDOL, while it knew or should have known that those claims were referred from a physician or physicians' group practice with which it enjoyed a compensation arrangement, and thus that the claims were sourced from prohibited referrals, BTW-I violated the Federal False Claims Act.

9. Moreover, by agreeing with each of the Physician Defendants to receive referrals for prescriptions, for which BTW-I would then submit claims for reimbursement from the U.S. Department of Labor under eligible programs, BTW-I and the Physician Defendants conspired to violate the Federal False Claims Act.

FEDERAL JURISDICTION AND VENUE

10. This action arises under the laws of the United States to redress violations of the Federal False Claims Act, the Federal Employees' Compensation Act, the Federal Anti-Kickback Statute, and the Stark Law. Subject-matter jurisdiction is conferred over these causes of action by 28 U.S.C. § 1331, 28 U.S.C. § 1345, and 31 U.S.C. § 3732.

11. The Court has personal jurisdiction over Defendants under 31 U.S.C. § 3732(a), which provides that actions under the Federal False Claims Act "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” the Federal False Claims Act occurred. During the relevant time period, Defendant Athens Bone & Joint, P.C. resided and transacted business in this District, and Defendants BTW and/or Infinity transacted business in this District.

12. Venue lies under 28 U.S.C. § 1391(b), 31 U.S.C. § 3732(a), and Civil Local Rule 3.4 because at least one of the Defendants, Athens Bone & Joint, P.C., transacts business and resides within this District and Division. Venue is also appropriate because substantial information supporting the allegations herein is located in this District and Division.

PROCEDURAL ALLEGATIONS

13. To the extent, if any, that this case is deemed to be a “related action” and to the extent, if any, that facts set forth herein are deemed to be the same as facts underlying an existing *qui tam* False Claims Act action pending at the time of the filing of this action, as set forth in 31 U.S.C. § 3730(e), said factual allegations in common with any pending action that would cause this case to be a “related action” are hereby expressly excluded from this action, but only to the limited extent necessary to avoid the statutory preemption.

14. Furthermore, to the extent that the allegations or transactions set forth herein are the subject of civil suit or an administrative civil money penalty

proceeding in which the United States is already a party, if any such proceedings exist, then the allegations or transactions referred to herein, which are the subject of any such civil suit or administrative civil penalty proceedings are expressly excluded, but only for the specific time periods, specific companies, and/or specific allegations or transactions that are already the subject of the civil suit and/or administrative civil money penalty proceeding.

15. The facts and circumstances of the Defendants' violation of the Federal False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office or Auditor General's report, hearing, audit, or investigation, or in the news media.

16. Relator is the "original source" of the information upon which this Complaint is based, as that phrase is set forth in 31 U.S.C. §3730(e)(4)(B), and she provided disclosures of the allegations of this Complaint to the United States prior to filing.

17. Immediately upon filing this Complaint, Relator will provide the Attorney General with a copy of the Complaint and written disclosure of substantially all material evidence and information in his possession. The illegal conduct of Defendant alleged herein began in 2015 and, on information and belief, continues through the date of filing of this Complaint. The allegations herein have

not been the subject of any settlement agreement between these Defendants and the United States Government.

PARTIES

18. Relator Elizabeth Peters Young is a resident of Ormond Beach, Florida, USA. For all times relevant and material to the Complaint prior to July 2016, however, Relator resided in Ball Ground, a city in Cherokee County, Georgia, and worked in and served territories within the State of Georgia, including territory subject to the jurisdiction of the United States District Court for the Middle District of Georgia.

19. For more than twenty-five years, Relator has contracted outside sales, for manufacturers and distributors of highly sophisticated medical devices critical to the practices of neurological and orthopedic surgeons and physicians. In the course of her career, Relator has presented the benefits of spinal fusion bone growth devices, aneurysm clips, stereotatic systems, pneumatic surgical drills, and other devices meant to heal and prevent spinal injuries, as well as trained hospital staff and physicians themselves in these devices' proper use. Most recently, Relator has worked as an independent contractor selling and distributing joint reconstruction and spinal implants and topical analgesic and anesthetic creams and patches.

20. Relator engaged in conversation with the national sales manager for BTW, Patrick Booth, in which Booth sought to hire Relator to work territory in Florida for BTW. It was during these conversations that Booth revealed that BTW provides topical creams and patches to physicians at cost.

21. Relator obtained direct, personal knowledge of the violations alleged in this Complaint through her deep knowledge of pharmaceutical sales and claims processing amassed through here twenty-five years of experience supporting vendors and distributors serving physicians and their private practices. Through an independent investigation, discovering information learned from Booth and from other employees of BTW-I or their affiliates, Relator has learned about the fraud Defendant committed and continue to commit on the Government.

22. The real party in interest is the United States of America because taxpayer funds were and are being paid to Defendants as a result of the false claims alleged in this Complaint.

23. Defendant BTW Solutions, LLC is a limited liability company organized under the laws of the State of Arkansas and with its registered agent, David Fisher, located in Bentonville, Arkansas.

24. BTW markets itself as a third-party billing service, accepting assignments of rights on behalf of physicians to pursue reimbursement for physicians' claims on eligible programs. BTW claims to offer in-office dispensary

services, including software and support services; inventory management; practice management integration; and billing management, in addition to claims processing.

25. Infinity Compounding Solutions, LLC, doing business under the fictitious name of Infinity Care Solutions, is a limited liability company organized under the laws of the State of Arkansas and with its registered agent, David Fisher, located in Bentonville, Arkansas.

26. Infinity markets itself as a provider of pharmaceutical services to patients and healthcare providers. It relies on “impeccable customer service” and “cutting edge pharmaceutical compounding methods” in the area of “topical pain medications” to attract customers seeking assistance with provision of medication.

27. Perimeter Orthopaedics, P.C., located at 5673 Peachtree Dunwoody Rd., Suite 825, Atlanta, GA 30342, is a domestic professional corporation registered to do business in the State of Georgia and with its headquarters and principal place of business in the State of Georgia.

28. Dr. Daniel Alan Nicholson practices at Perimeter Orthopaedics, P.C. On information and belief, Dr. Nicholson owns Perimeter Orthopaedics, P.C. in whole or in part.

29. Atlanta Orthopedic Center, P.C., located at 6525 Professional Pl., Suite A, Riverdale, GA 30274, is a domestic professional corporation registered to

do business in the State of Georgia and with its headquarters and principal place of business in the State of Georgia.

30. Dr. Feroze Yusufji practices at Atlanta Orthopedic Center, P.C. On information and belief, Dr. Yusufji owns Atlanta Orthopedic Center, P.C. in whole or in part.

31. Athens Bone & Joint, P.C., located at 1010 Prince Avenue, Suite 115 South, Athens, GA 30606, is a domestic professional corporation registered to do business in the State of Georgia and with its headquarters and principal place of business in the State of Georgia.

32. Dr. John Dorris, Dr. David Bacastow, Dr. David Ryan, and Dr. Logan Fields practice at Athens Bone & Joint, P.C. On information and belief, Drs. Dorris, Bacastow, Ryan, and Fields each own part of Athens Bone & Joint, P.C.

33. Sports Medicine South, LLC, located at 1900 Riverside Pkwy, Lawrenceville, GA 30043, is a limited liability company organized under the laws of the State of Georgia and with its headquarters and principal place of business in the State of Georgia.

34. Dr. Gary A. Levengood, Dr. Saadiq El-Amin, III and Dr. Christopher R. Sellars practice at Sports Medicine South, LLC. On information and belief, Drs. Levengood, El-Amin, and Sellars each directly or indirectly own membership interests in Sports Medicine South, LLC.

35. Myers Sports Medicine and Orthopaedic Center, L.L.C. located at 3200 Downwood Circle, #340, Atlanta, GA 30327, is a limited liability company organized under the laws of the State of Georgia and with its headquarters and principal place of business in the State of Georgia.

36. Dr. Thomas Myers practices at Myers Sports Medicine and Orthopaedic Center, L.L.C. On information and belief, Dr. Myers directly or indirectly owns a membership interest in Myers Sports Medicine and Orthopaedic Center, L.L.C. in whole or in part.

GENERAL ALLEGATIONS

37. Defendants have been and, on information and belief, are engaged in a scheme to submit claims for the provisions of pain-relief and anesthetic topical creams and patches that are the product of exclusive referrals obtained through unlawful remuneration arranged pursuant to contract between BTW-I and each of the Physician Defendants.

A. Background on Federally-Funded Workers' Compensation Programs Through the Federal Employees' Compensation Act

38. Congress established the Office of Workers' Compensation Program ("OWCP") in 1916, for the stated purpose of administering claims made under the Federal Employees' Compensation Act. FECA provides benefits to federal and postal employees, as well as other specified classes of people, such as Peace Corps volunteers and civil Defense employees. The OWCP also administers the

Longshore and Harbor Workers' Compensation Act of 1927, the Black Lung Benefits Reform Act of 1977, and the Energy Employees Occupational Illness Compensation Program Act.

39. FECA provides medical benefits, vocational rehabilitation benefits, and wage replacement for work-related injuries and occupational disease. It is a self-insurance system funded through payroll taxes and government contributions. FECA was intended to be a non-adversarial system under which disputes are resolved through informal conferences or formal reconsideration at the district office level. When dispute persist, FECA and its implementing regulations provide for administrative hearings and the opportunity to appeal to the Employees' Compensation Appeals Board.

40. The United States Department of Labor (USDOL) includes the Division of Federal Employees' Compensation (DFEC), which administers FECA. The costs of benefits provided to covered employees are paid by the given employee's host agency.

41. The claimant generally bears responsibility for establishing the five basic requirements of a claim adjudicated through the OWCP: compliance with statutory time requirements; status as an eligible employee; fact of injury, including whether the claimant actually experienced the injury and whether the claimant has been diagnosed with a medical condition; occurrence of the injury in

the performance of duty; and causal relationship between employment factors or event and injury. *See generally* Federal Employees' Compensation Act Procedure Manual, Parts 2-0801 through 2-0805.

42. However, a FECA claimant and beneficiary is not responsible for any coinsurance or any other costs associated with his/her medical treatment, and is not required to apply personal insurance benefits prior to submission of a claim under FECA.

B. Applicable Statutes

43. The complexity and magnitude of Federal health care programs (whether Medicare, Medicaid, Tricare, etc.) create incentives and opportunities for pervasive fraud and abuse. Congress accordingly has enacted multiple statutes to combat fraud and abuse in these programs.

1. The Federal Anti-Kickback Statute

44. In 1972, Congress enacted the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), to protect patients and federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on healthcare provision and supply decisions. The AKS makes it a crime to knowingly and willfully offer, pay, solicit, or receive remuneration to induce a person to refer an individual to a person for the furnishing of any item or service covered under a federal healthcare program, or to purchase, lease, order, arrange for, or recommend

any good, facility, service, or item covered under a federal healthcare program. § 1320a-7b(b)(1)-(2).

45. The term “remuneration” includes any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. § 1320a-7b(b)(1).

46. An act is willful for purposes of the AKS if “the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law.” *U.S. v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998).

47. The AKS covers any arrangement where at least one purpose of the remuneration was to obtain money for the referral or services or to induce further referrals. Even payments intended in part to compensate physicians for professional services violate the AKS if the payments were also made to induce referrals.

48. A violation of the AKS constitutes a felony punishable by a maximum fine of \$25,000, imprisonment of up to five years, or both. Any party convicted under the AKS must be excluded from federal healthcare programs for at least five years. § 1320a-7(a). Moreover, if the HHS Secretary finds via an administrative process that a provider has violated the AKS, the Secretary may impose administrative sanctions of \$50,000 per violation and exclude the provider from

federal and state healthcare programs for a discretionary period. §§ 1320a-7(b), 1320-7a(a), (c).

49. For the purposes of the Federal Anti-Kickback Statute, “Federal health care program” means, *inter alia*, “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,” save for the Federal Employee Health Benefits program. *See* 42 U.S.C. § 1320a-7b(f)(1).

2. *The Stark Law*

50. In 1989, Congress enacted the Physician Self-Referral Law, 42 U.S.C. § 1395nn, colloquially known as the Stark Law. The Stark Law, as amended, prohibits a physician from referring patients for “designated health services” to an entity with which the physician or the physician’s immediate family has a financial relationship, absent an applicable exception. § 1395nn(a)(1)(A). The Stark Law also prohibits an entity furnishing designated health services pursuant to a physician referral from presenting or causing to be presented a claim for payment through a Federal health care program. § 1395nn(a)(1)(B)

51. “The term “fair market value” means the value in arm’s length transactions, consistent with the general market value.” 42 U.S.C. § 1395nn(h)(3).

52. “Designated health services” are broadly defined to include twelve categories of services, including outpatient prescription drugs. *See* 42 U.S.C. § 1395nn(h)(6)(j).¹

53. The term “financial relationship” is broadly defined by the Stark Law, including ownership and investment interest in an entity receiving a referral, as well as compensation arrangements involving any direct or indirect remuneration between a physician and an entity receiving a referral. § 1395nn(a)(2); *see also* 42 C.F.R. § 411.354(a)(1)(ii), (c)(2) (providing that “financial relationship” includes indirect compensation arrangements).

54. Any entity collecting payments on claims for designated health services furnished pursuant to a referral prohibited by the Stark Law must refund all collected payments on a timely basis. 42 U.S.C. § 1395nn(g)(2). Further, any entity presenting or causing to be presented such a claim, the payment for which is not refunded on a timely basis, is subject to a civil penalty of up to \$15,000 per furnished service and an assessment of three times the amount claimed for each service. § 1395nn(g)(3) (referring to § 1320a-7a(a)).

3. *The Federal False Claims Act*

¹ Although generic equivalents of the drugs marketed by BTW-I are available over the counter, these drugs are covered by the Stark Law because a) they are made available to patients via a prescription from a physician on an outpatient basis, and b) expenditures for dispensing the drugs are submitted to a Federal health care program for reimbursement.

55. The Federal False Claims Act prohibits the knowing presentment, making, use, or causation of a false or fraudulent claim for payment, or record or statement within a claim for payment, for services provided under the auspices of a Federal health care program, or who conspires to commit such a knowing act. 31 U.S.C. § 3729(a)(1). A person or entity violating the Federal False Claims Act is liable for a civil penalty of \$5,000 to \$10,000 per act, subject to exceptions and adjustments; treble damages for harm sustained by the United States attributable to the fraud; and the costs of the civil action brought to recover penalties or damages. § 3729(a)(1)-(3).

56. As set forth in the Federal False Claims Act, “knowing” means that a person has actual knowledge of the information or acts in willful ignorance or reckless disregard of the truth or falsity of the information submitted. The United States need not show that the person or entity held a specific intent to defraud. § 3729(b)(1).

C. Background on Topical Analgesics and Anesthetics

57. Topical analgesics and anesthetics block pain sensation and ease burning and itching when applied to the skin. Some analgesics are available over-the-counter from a pharmacy, while others with greater anesthetic properties require a prescription from a physician.

58. LidoPro, a topical analgesic containing methyl salicylate, menthol, capsaicin, and lidocaine, is indicated for temporary relief of minor aches and pains of muscles or joints.

59. Medrox, a topical analgesic containing menthol, capsaicin, and other “natural” components, is indicated for temporary relief of minor aches and muscle pain associated with arthritis, simple backaches, strains, muscle soreness and stiffness.

60. Terocin, a topical analgesic with the generic name terodoloricin, contains methyl salicylate, menthol, capsaicin, and lidocaine and is indicated for temporary relief of minor aches and pains of muscles or joints.

61. According to records Relator gathered in her independent investigation, the cost on a per-unit basis of each of these medications is as follows:

<u>Product Description</u>	<u>Cost of Product</u>
Terocin Cream	\$35/bottle
Lidopro Cream	\$35/bottle
Menthoderm Cream	\$35/bottle
Medrox Patches	\$23/box of 5
Toxicology Kit	\$45/kit

62. According to records Relator gathered in her independent investigation, the stated claim value filed with USDOL rises as high as \$852 for two four-ounce bottles of Lidopro and \$870 for six five-patch boxes of Medrox.

D. The Fraudulent Scheme

63. BTW-I employs and has sought to employ sales representatives to market BTW-I as a provider of both prescription medications and claims-processing and management services to physicians seeking a boost in revenue from their patients' prescription medicine needs.

64. BTW-I obtains extra security in its relationships by demanding that physicians agree to refer prescriptions for topical analgesics for eligible patients exclusively through BTW-I. BTW-I and a given physician enter into written contracts which delineate their shared financial interests and prohibits physicians from entering into business with entities that compete with BTW-I.

65. The written contract signed by BTW-I and the physician purports to establish compensation for BTW-I as deriving from the management, billing, and claims-processing and collection services provided by BTW-I to the physician. Because the fifty percent share of the fulfilled claim (less the cost of the product) is so much larger than standard industry practice, however, physicians have no incentive to sign such a contract with BTW-I absent some other incentive.

66. That incentive is BTW-I's pricing of Lidopro, Medrox, Terocin, and other similar medications, included in a schedule appended to the contract. BTW-I sells pain relief medications to Physicians at cost, a price considerably below fair market value. BTW-I only "build(s) in a little for shipping and handling" of the medicines to physicians' offices, seeking to make its profits through obtaining complete or nearly complete reimbursements on claims through the U.S. Department of Labor and by keeping an exponentially greater share of those proceeds than is customary in the industry.

67. Per written contract, a physician agrees to prescribe the pain relief medications obtained from BTW-I only to patients who are receiving medical care under an eligible program. Each physician's office dispenses the prescribed medication itself, rather than directing patients to obtain medications from a retail pharmacy.

68. On information and belief, BTW-I instructs physicians to use point-of-care dispensation to increase the likelihood of physicians prescribing (and later ordering) such products from BTW-I through their exclusive arrangement, thereby generating further reimbursements and profits.

69. BTW-I billed and bills third-party insurers contracted with USDOL for the prescribed medication at the market rate for such payors and payees. Upon full or partial reimbursement, BTW-I and the Physician Defendants equally divide

the payment, with the physician also contributing to BTW-I the actual cost of the medical product. BTW-I materials offered to sales representatives for use in conversations with potential physician customers explain that the cost of the medicine must be deducted because the physician needs to incur perceived risk as part of the arrangement to avoid concerns over violating local “fee-splitting” laws.

70. BTW-I offered these sales representatives a set commission on the net reimbursements gathered from any referred prescriptions obtained through contracts sold by the representatives. After accounting for the cost of the medication and the physicians’ share of any reimbursements obtained, the representative would receive a thirty percent (30%) commission. Sales representatives receive no commissions for sales of the medical products to physicians.

71. BTW-I expressly instructs sales representatives to explain to doctors that BTW-I makes no profit from sales of the medical products themselves. This instruction is consistent with the scheme in which physicians receive remuneration in the form of costs for prescription medicines well below market value and via means (point-of-care dispensation) likely to encourage patient returns and positive word of mouth among eligible patients.

72. On information and belief, Lidopro, Medrox, Terocin, and other similar medications are not provided to physicians at a greater strength than that

available to patients on an over-the-counter basis. This increases the profitability of the BTW-I and the Physician Defendants' scheme; by providing over-the-counter strength medication to patients (thus keeping material costs low) and seeking market-price reimbursements from Federal health care programs for prescription-strength pain relief medications, they increase the amount of taxpayer money each can retain after obtaining reimbursement through the OWCP.

73. On or about August 11, 2016, Defendant Atlanta Orthopedic, P.C. was invoiced by BTW for thirty four-ounce tubes of Lidopro cream at a total cost of \$1,050 and for thirty boxes of unknown quantities of Lidopro patches at a total cost of \$2,488.50.

74. On or about August 18, 2016, Defendant Atlanta Orthopedic, P.C. paid \$700 to BTW for twenty four-ounce tubes of Lidopro cream and \$1,659 to BTW for twenty boxes of unknown quantities of Lidopro patches.

75. On or about August 23, 2016, Defendant Atlanta Orthopedic, P.C. received a statement from BTW demonstrating that BTW had provided it with \$7,784.70 worth of inventory from April 26, 2016 through August 11, 2016 alone.

76. Relator cannot at this time identify each and every false or fraudulent claim for payment or approval, as she has no control over Defendants and no access to the records they possess or control. From what she has determined in her investigation, however, she understands there to be thousands

more prescriptions and claims that have been referred and submitted, and dozens or scores more physician customers throughout the United States.

CAUSES OF ACTION

COUNT ONE (All Defendants)

VIOLATION OF FEDERAL ANTI-KICKBACK STATUTE — 42 U.S.C. § 1320a-7a(a)

77. Relator incorporates by reference and re-alleges paragraphs 1-76 of this Complaint set forth above as if fully set forth herein.

78. Defendants BTW and Infinity's arrangements to compensate each of the Physician Defendants in exchange for referrals for outpatient prescription drugs, namely prescriptions for topical analgesics, violates the Federal Anti-Kickback Statute because the compensation in the form of prescription drugs at a rate below fair market value constitutes remuneration offered to induce or solicit, or as compensation for, the referral of business paid for by federal programs, including programs authorized under FECA.

79. Defendants BTW and Infinity knowingly and willfully provided Lidopro, Medrox, Terocin, and other prescription drugs at cost as financial inducement, solicitation, or compensation for patient referrals.

80. The Defendant Physicians, and each of them, knowingly and willfully received remuneration in the form of Lidopro, Medrox, Terocin, and

other prescription drugs at cost as financial inducement, solicitation, or compensation for patient referrals.

81. Defendant BTW and/or Infinity intended to and in fact did submit claims for reimbursement from federal programs, including programs authorized under FECA, for any outpatient prescription drugs it furnished to referred patients through point-of-care dispensaries located in Defendant Physician offices.

82. For each Anti-Kickback Statute violation, Defendants are jointly and severally liable to the United States Government for damages of up to three times the amount of the improper remuneration at issue, as well as to penalties of up to \$50,000 for each improper act, pursuant to 42 U.S.C. § 1320a-7a(a).

COUNT TWO
(All Defendants)

**VIOLATION OF PHYSICIAN SELF-REFERRAL LAW,
a/k/a THE STARK LAW — 42 U.S.C. § 1395nn(a)(1)**

83. Relator incorporates by reference and re-alleges paragraphs 1-82 of this Complaint set forth above as if fully set forth herein.

84. Defendant Physicians engaged in a compensation relationship with Defendant BTW-I through contracts providing for the Defendant Physicians' purchase of prescription medication for outpatient point-of-care dispensation exclusively through Defendant BTW-I.

85. Defendant Physicians referred patients eligible for benefits through the OWCP for outpatient prescription drugs to Defendant BTW (with the prescriptions to be filled by Infinity), an entity with which they had a compensation arrangement in violation of the Stark Law. *See* 42 U.S.C. § 1395nn(h)(1).

86. None of the Stark Law's exceptions apply to the illegal compensation relationship or referrals between Defendants.

87. Each referral of an eligible patient for outpatient prescription drugs by each Physician Defendant to Defendant BTW, to be filled by Infinity, even for prescriptions fulfilled via point-of-care dispensary in a Physician Defendant's office, constituted a violation of the Stark Law.

88. Each of Defendant BTW and/or Infinity's claims for federally-supplied funds related to tainted referrals received from Physician Defendants, and so each claim constituted a violation of the Stark Law.

89. Defendants are jointly and severally liable to the United States Government.

COUNT THREE
(Defendants BTW and Infinity)

VIOLATION OF FEDERAL FALSE CLAIMS ACT —
31 U.S.C. § 3729(a)(1)(A)

90. Relator incorporates by reference and re-alleges paragraphs 1-89 of this Complaint set forth above as if fully set forth herein.

91. The False Claims Act provides that any person who knowingly presents or causes to be presented to the United States Government, a false or fraudulent claim for payment or approval, is liable for (a) three times the amount of the damages sustained by the United States Government, and (b) civil penalties ranging from \$5,500 to \$11,000 for each claim. 31 U.S.C. § 3729; 28 C.F.R. § 85.3(a)(9).

92. Defendant BTW provided compensation to Defendant Physicians to induce improper referrals of prescriptions to BTW, to be filled by Infinity, for the provision of topical analgesics to beneficiaries of eligible programs in violation of the Federal Anti-Kickback Statute and of 31 U.S.C. § 3729(a)(1)(A).

93. Defendants BTW and Infinity's violations of the Federal Anti-Kickback Statute render them jointly and severally liable to the United States Government under the Federal False Claims Act. *See* 42 U.S.C. § 1320a-7b(g).

94. Defendants BTW and Infinity's violations of the Stark Law render them jointly and severally liable under the False Claims Act.

95. Defendants BTW and Infinity, knowingly, or with reckless disregard to the truth or falsity thereof, submitted or caused to be submitted claims for eligible patients to the U.S. Department of Labor for payment by the United States Government, arising directly from illegal referrals from Physician Defendants, from a date unknown to Relator but lasting in any event for several years through the date of filing of this Complaint.

96. On information and belief, the United States Government, through programs established under the authority of the Federal Employees' Compensation Act, and unaware of the falsity of the claims made or caused to be made by Defendant BTW, paid and continue to pay Defendant BTW and Infinity for claims it made and makes on behalf of the Physician Defendants that would not be paid if the truth were known.

97. As a direct and proximate result of the false and fraudulent claims made by Defendants BTW and Infinity, the United States Government has been damaged, on information and belief, in the amount of millions of dollars.

**COUNT FOUR
(All Defendants)**

**VIOLATION OF FEDERAL FALSE CLAIMS ACT —
CONSPIRACY TO SUBMIT FALSE CLAIMS, 31 U.S.C. § 3729(a)(1)(C)**

98. Relator incorporates by reference and re-alleges paragraphs 1-97 of this Complaint set forth above as if fully set forth herein.

99. On information and belief, Defendants conspired and agreed with each other and with others to defraud the United States, as alleged in Count Three above.

100. As a direct and proximate result of the false and fraudulent claims made by Defendants BTW and Infinity on behalf of the Physician Defendants, the United States Government has suffered damages for which Defendants are jointly and severally liable. The United States Government therefore is entitled to recovery as provided by the Federal False Claims Act for each such violation.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants by acting as follows:

- a) Granting permanent injunctive relief to prevent any recurrence of the Federal False Claims Act claims for which redress is sought in this Complaint;

- b) Awarding to the United States of America damages in the amount of three times the damages it sustained due to the false claims and fraud alleged in the foregoing paragraphs;
- c) Awarding to the United States of America assessments in the amount of three times the amount claims for each outpatient prescription filled and dispensed pursuant to a prohibited referral;
- d) Imposing civil penalties of \$50,000, or of such lesser amount as the Court deems proper, for each and every violation of the Federal Anti-Kickback Statute committed by Defendants;
- e) Imposing civil penalties of \$15,000, or of such lesser amount as the Court deems proper, for each and every referral prohibited by the Stark Law that Defendants conducted;
- f) Imposing civil penalties of \$11,000, or of such lesser amount as the Court deems proper, for each and every false claim that Defendants presented to the United States of America;
- g) Awarding pre- and post-judgment interest, costs, and expenses of litigation including reasonable attorneys' fees which the Relator necessarily incurred in filing and advancing this action;
- h) Awarding to Relator the maximum amount allowed to her under the Federal False Claims Act based upon the total value recovered, both

tangible and intangible, including any amounts recovered from individuals and entities not party to this action; and

i) Awarding such other and further relief as it deems proper.

JURY TRIAL DEMAND

Relator demands a trial by jury of all claims asserted in this Complaint.

* * *

Respectfully submitted, this 7th day of June, 2017.



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