IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

UNITED STATES OF AMERICA *ex rel.* DOE,
Plaintiffs,

v.

DERMATRAN HEALTH SOLUTIONS, LLC, GULFCOAST ADMINISTRATORS, LLC, PHARMACY INSURANCE ADMINISTRATORS, LLC, INSURANCE ADMINISTRATIVE SOLUTIONS LLC, PHARMACY MARKETING SERVICES, INC., STATE MUTUAL INSURANCE COMPANY, HEALTHLOGIC PARTNERS, LLC, LAKESIDE PHARMACY, LLC, LEGENDS PHARMACY, LLC, TRIAD RX, INC., CUSTOM PHARMACY SOLUTIONS, LLC, TITAN MEDICAL MARKETING, LLC, SIRCLE LABORATORIES, LLC, IVERSON GENETIC DIAGNOSTICS, INC., THAYER INTELLECTUAL PROPERTY, INC., TEKSOUTH, CORP, DIII CONSULTING, LLC, SRM HOLDINGS, LLC, SRM HOLDINGS II, LLC, GUSSENHOVEN HOLDINGS, LLC, DELOS H. YANCEY III, SAM R. MOSS, ROBERT GUSSENHOVEN, AND ROE PHYSICIANS, ROE PHARMACIES, ROE MEDICAL MARKETING CLIENTS, AND ROE THIRD- PARTY MARKETERS,
Defendants,

Civil Action No.

4:17-cv-00196-HLM

JURY TRIAL DEMANDED

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

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I. INTRODUCTION

1. This is an action to recover damages, civil penalties, and other relief on behalf of the United States for false and/or fraudulent statements, records, and claims made and caused to be made, and overpayments not returned, by the Defendants and/or their agents and employees and subsidiaries with respect to Government Health Care Programs in violation of the federal False Claims Act, ("FCA") 31 U.S.C. §§ 3729, *et seq*. As described in more detail below, these Defendants engaged in a conspiracy to defraud the government and to violate the False Claims Act, *i.e.*, to cause the government to pay for claims that were false, fraudulent, and/or otherwise ineligible for payment.

2. In 2012, Defendants Delos H. Yancey, Sam R. Moss, and Robert Gussenhoven founded Defendant DermaTran Health Solutions, LLC ("DermaTran"). DermaTran claims to be a group of pharmacies that specialize in the compounding of topical pain creams based on physicians' prescriptions. In truth, however, DermaTran exists primarily as a vehicle to defraud Government and private health insurers into providing expensive reimbursements for medications, the prescriptions for which are induced by bribing the Defendant Roe Physicians. Defendants received as much as $4,000 each month from Government Health Care Programs for preparations that cost them a tiny fraction.

3. DermaTran's schemes to defraud, which ultimately produced tens of millions of dollars of illegal profits, also include engaging Marketing Defendants, Pharmacy Marketing Services, Inc., HealthLogic Partners, and others, paying them illegal inducements in the form of a percentage of earned revenue – often millions of dollars annually – to do whatever it took to bring in additional prescriptions. This included making false representations about the safety and efficacy of the products, including that the product was not processed by the liver and that it had no side-effects or addictive potential, despite the fact that formulations often contained Ketamine and opioids.

4. After securing patients to purchase its products, Defendant DermaTran and its co-defendants engaged in a variety of schemes aimed at maximizing their revenue at the Government's expense. For example, Defendants avoided charging copayments by purporting to "invoice" copayments later while never intending to collect them; inventing a "patient-experience survey" designed solely to offset copayments; illegally applying a manufacturer copayment card to government reimbursed claims; and utilizing a fictitious charity program whose only requirement for enrollment was that a patient decline to pay a copayment.

5. As part of the effort to disguise these illegal activities and launder the profits derived from them, Defendants exploited Defendant State Mutual Insurance

Company – a mutual insurance conglomerate controlled by Defendant Yancey, whose assets and resources he misappropriated to enrich himself – and its subsidiaries, including Pharmacy Insurance Administrators, LLC ("PIA"), Insurance Administrative Services, LLC, and Gulfcoast Administrators, LLC ("Gulfcoast"), all Defendants herein. Defendant State Mutual and its co-Defendant subsidiaries improperly paid employees to work in part or in whole for DermaTran. Defendant PIA operated as an additional sales force, contacting DermaTran patients and convincing them to fill their prescriptions, refill them when needed, and enroll in auto-refill programs (prohibited under government reimbursement rules) among other schemes.

6. Defendant PIA and its staff were illegally compensated with a percentage of DermaTran revenue. This put enormous pressure on the PIA employees to do whatever it took to ensure that the flow of prescriptions continued. In some cases, PIA employees bribed patients with free drugs. In other situations, sales agents impersonated a patient's family member, fraudulently reordering medications and paying the copayment with the sales agent's personal credit card.

7. The maximum allowable reimbursement for compounded drugs varies depending on the supplier of its constituent ingredients. Defendants spent

enormous effort to test the reimbursement rate of medications composed of different combinations of supplier's chemicals. Choosing one vendor's ingredients over another could as much as double profit on each prescription. Defendants used their knowledge of these reimbursement rates to charge government payers thousands of dollars and minimize charges for the same products when favored patients needed to pay out of pocket, all the while reporting fraudulent "usual and customary" prices to the Government.

8. When plans would outright refuse to pay, DermaTran would switch patients to a prescription for lidocaine, a pain cream commonly available over the counter for a few dollars (and therefore illegal to compound) for which DermaTran would charge a few hundred dollars, a relative bargain.

9. Not only was DermaTran's purported interest in patient care a ruse, but its very claim to be a legitimate compounding pharmacy was fraudulent. DermaTran's hundred-plus sales agents primarily peddled DermaTran's compounds, which were offered on pre-printed prescription pads, for drugs compounded in mass quantities rather than in response to individual patient requests or physicians' prescriptions. These compounds included formulas that were essentially copies of commercially available products. DermaTran was, under the law, an unlicensed manufacturing facility producing misbranded products in

violation of the Federal Food, Drug, and Cosmetic Act and well-publicized laws applicable to compounders such as DermaTran.

10. In 2015 the systemic abuse by compounding pharmacies similar to DermaTran began to attract nation-wide interest. Once they learned of some of DermaTran's schemes, some Pharmacy Benefits Managers ("PBMs"), including the entities managing TRICARE, terminated DermaTran's provider agreement, preventing further reimbursement. DermaTran endeavored to bypass these terminations by transferring its prescriptions to its other locations. When insurers would do business with no DermaTran entity, DermaTran illegally "sold" its prescriptions to other pharmacies, including Defendants Lakeside Pharmacy, Legends Pharmacy, Triad Rx Pharmacy, Custom Pharmacy Solutions, and Roe Pharmacies in exchange for a portion of the reimbursement.

11. The practices alleged in this Complaint defraud every insurer – both public and private – that reimburses for compounded drugs. Federal and state health care programs targeted by Defendants' scheme include Medicare, Medicaid, TRICARE, Federal and state workers' compensation programs, and many other programs. As discussed in further detail below, Defendants viewed TRICARE and the Federal Employees Compensation Act ("FECA") as particularly attractive

marks due to their combination of high reimbursement and perceived lack of effective oversight.

12. Each of Defendants' activities alleged herein violates various provisions of federal law designed to protect the public fisc and patient welfare. Moreover, as described in further detail below, the submission of claims resulting from these schemes violates the FCA.

13. Defendants' payment to physicians violates the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. §1320a-7b(b), the "Stark Law" prohibiting physician self-referral, 42 U.S.C. § 1395nn, and TRICARE's fraud and abuse regulations. These laws are designed to ensure that physicians make clinical decisions based upon informed, impartial medical judgment unaffected by bribes or self-interest. Defendants have knowingly and routinely sought to corrupt the medical judgment of physicians by offering bribes to obtain referrals of the physicians' patients.

14. Defendants' payment to third parties to induce patients and doctors to refer prescriptions to DermaTran or refill them, and acceptance of bribes in exchange for transferring prescriptions to other pharmacies, likewise violates the AKS and similar TRICARE laws, which protect the integrity of medical referrals by prohibiting payments of this sort in exchange for referrals. The corrupting

influence of DermaTran's payments is clear in light of the deeply dishonest actions utilized by these parties to ensure that the prescriptions continued to be filled.

15. Likewise, Defendants' multiple schemes to avoid charging copayments constituted bribes to induce the patients to overutilize government-reimbursed medication regardless of need. The AKS and similar laws prohibit just such fraudulent attempts to induce health care overutilization.

16. Defendants' manipulations of the price of their compounded products and related machinations violate bedrock rules requiring, *inter alia*, that government-reimbursed goods and services be provided economically and not be manipulated to maximize provider profits.

17. DermaTran also contracted or otherwise agreed to induce physicians and patients to purchase opioid medications produced by Defendant Sircle Laboratories, genetic lab testing products and services provided by Defendant Iverson Genetic Diagnostics, medical devices produced by Defendant Thayer Intellectual Property, Inc. and medications, medical devices and medical services produced by Defendant Roe Medical Marketing Clients. In violation of the AKS, program guidelines, and TRICARE fraud and abuse regulations, DermaTran was compensated by commissions based on the volume of opioid medications, testing

services, and medical devices it successfully induced physicians and patients to prescribe and purchase.

18. Claims for reimbursement obtained in violation of the AKS, program guidelines, and TRICARE fraud and abuse regulations, along with additional conduct alleged herein violates the federal False Claims Act. The federal False Claims Act, which Congress characterized as the primary tool for combating government fraud, was originally enacted during the Civil War and substantially amended subsequently to enhance the ability of the Government to recover losses sustained as a result of fraud against it. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

19. The FCA prohibits, *inter alia*: knowingly presenting (or causing to be presented) a false or fraudulent claim for payment or approval; knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; and, knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government; knowingly concealing or

knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and, conspiring to commit any of these acts. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G), and (C). Any person who violates the FCA is liable for a civil penalty of up to $22,363 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1); 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018). This amount is adjusted annually pursuant to the federal regulation. *Id.*

20. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit. The person bringing the action is known under the FCA as the "Relator."

21. Based on the foregoing federal FCA provisions, *qui tam* Plaintiff-Relator seeks, through this action, to recover damages and civil penalties arising from the Defendants' knowing fraud against the United States and the states including through the Medicare and Medicaid programs. Defendants have defrauded the Government of tens of millions of dollars since at least 2012.

22. The allegations set forth in this Complaint have not been publicly disclosed within the meaning of the FCA, as amended, 31 U.S.C. § 3730(e)(4). In the alternative, if the Court finds that there was a public disclosure of such allegations before the filing of this Complaint, Relator is an "original source" as that term is used in the FCA.

23. This action is filed in camera and under seal pursuant to the requirements of the FCA.

II. JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

25. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because one or more Defendants can be found in, resides in, and transacts substantial business in this district, including business related to Defendants' misconduct.

26. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391, and 28 U.S.C. § 1395(a), because Defendants transact business in this District by among other things operating a compounding pharmacy and

maintaining a corporate headquarters which are at the center of the fraud described herein.

III. PARTIES

27. Plaintiff the United States of America is the real party in interest with respect to the federal False Claims Act *qui tam* claims herein. Plaintiff-Relator Doe is pursuing causes of action on behalf of the named Plaintiff the United States on the FCA *qui tam* claims set forth herein pursuant to 31 U.S.C. § 3730(b).

28. Relator Doe is a citizen of the United States who is familiar with and has knowledge of the Defendants' business operations and the allegations herein. Relator is pursuing this case as a Doe Plaintiff because Relator has worked with many of these defendants, knows them personally, and intends to continue to work in the industry and consequently fears retaliation should identifying details become public. Relator's identity and additional information regarding Relator's knowledge of Defendants' fraudulent schemes have been and will continue to be provided to the United States.

A. The State Mutual Defendants

29. Defendant **DermaTran Health Solutions, LLC** is a Florida LLC organized in January 2012 as **Transdermal Health Solutions, LLC** with Gulfcoast Administrators, LLC identified as Managing Member. Its name was

changed to DermaTran Health Solutions, LLC three weeks later (documents signed by Delos H. Yancey III in his role as Managing Member of Gulfcoast Administrators, LLC). DermaTran was founded by Delos H. Yancey III, Sam R. Moss, and Robert Gussenhoven. Yancey operates as DermaTran's chief officer, but has never held equity in DermaTran in his own name, instead using various shell entities that he controlled. DermaTran's corporate headquarters are located in Rome, Georgia and it operates compounding pharmacies in Rome, Georgia, Louisville, Kentucky, and previously in Redding, California.

30. Defendant **Gulfcoast Administrators, LLC** ("Gulfcoast") is a Florida LLC organized in March 2008 by Rick Gordon, State Mutual Insurance Company Chief Financial Officer ("CFO"). Gulfcoast is two-thirds owned by State Mutual Insurance Company – 8.824% directly and 57.647% through another subsidiary, Life and Health Holdings, Inc., which is listed as the managing member of Gulfcoast. Gulfcoast is controlled by Yancey, who caused State Mutual to extend a line of credit to it which he utilized to invest in target entities and secure equity and compensation for himself personally. Through the Gulfcoast credit facility, Yancey provided DermaTran over $6 million.

31. Defendant **Pharmacy Insurance Administrators, LLC** ("PIA") is a Florida LLC organized in January 2012 on the same day as DermaTran with

Gulfcoast Administrators, LLC identified as Managing Member. PIA is a wholly owned subsidiary of Insurance Administrative Services, LLC. PIA was set up as a third-party insurance administrator, but in practice it operated as the call center for DermaTran focused primarily on inducing DermaTran patients to fill and refill their prescriptions and ensuring that their insurance could be billed. It also employed administrative personnel devoted solely to performing DermaTran tasks (some never realized they worked for PIA). PIA was compensated by DermaTran with a percentage of DermaTran revenue. It formally dissolved on March 31, 2017, but still maintains bank accounts.

32. Defendant **Insurance Administrative Solutions, LLC** ("IAS") is a Florida LLC organized in 2002 by John J. Anthony. In 2013 Yancey became the managing member of IAS and it is a wholly owned subsidiary of Gulfcoast. IAS and DermaTran maintain an operating agreement for the work performed by PIA.

33. Defendant **State Mutual Insurance Company** was incorporated in Florida in 1936 and redomesticated in Georgia in 1981. Its headquarters are in Rome, Georgia. It has merged with a number of other state insurance companies and now transacts business in 41 states and the District of Columbia selling Life, Accident, and Health Insurance. As a mutual insurance company, State Mutual is owned by its policy holders and in December 2014 had a surplus of $33 million on

assets of just under $300 million. Delos H. Yancey III serves as State Mutual's Chairman, President, and Chief Executive Officer ("CEO") and utilizes the corporation's assets for his own personal benefit.

B. Individual Defendants

34. Defendant **Delos H. Yancey, III** ("Yancey") is a resident of Rome, Georgia and State Mutual's Chairman, President, and Chief Executive Officer. Along with Moss and Gussenhoven, Yancey organized DermaTran in 2012. He operated as DermaTran CEO from its founding and held that title until 2017 when he purported to relinquish his equity in DermaTran and resign his office. At all times relevant to this complaint, he controlled the activities of the State Mutual Defendants and utilized State Mutual assets for his own benefit.

35. Defendant **DIII Consulting, LLC** is a Georgia LLC organized in July 2013 by Yancey with principal place of business at 185 Bellemont Drive SW, Rome, Georgia 30165, Yancey's home address. DIII Consulting held Yancey's equity in DermaTran from September 2013 through 2017.

36. Defendant **Sam R. Moss** is a resident of Rome, Georgia and along with Yancey and Gussenhoven organized DermaTran in 2012. Moss served as corporate Secretary of DermaTran until at least December 31, 2016, after which he may have become DermaTran's sole executive officer.

37. Defendants **SRM Holdings, LLC, & SRM Holdings II, LLC** are Georgia LLCs organized in September 2013 and December 2014, by Samuel R Moss and Richard Burton, with principal place of business at 85 Technology Pkwy, Rome, Georgia, and 210 E. Second Avenue Ste 301 Rome, Georgia respectively. SRM Holdings held the majority of Moss's equity in DermaTran.

38. Defendant **Robert Gussenhoven** is a resident of Alabama and, along with Yancey and Moss, organized DermaTran in 2012. Gussenhoven served as Chief Science Officer and Treasurer of DermaTran until May 2015. He still receives settlement payments from DermaTran pursuant to his separation.

39. Defendant **Gussenhoven Holdings, LLC**, is a Georgia LLC organized in September 2013 by Robert Gussenhoven with principal place of business at 85 Technology Pkwy, Rome, Georgia. Gussenhoven Holdings held the majority of Gussenhoven's equity in DermaTran.

40. Defendants **Roe Physicians** are co-conspirators located throughout the country who accepted cash and in-kind bribes to prescribe DermaTran products. These prescriptions were frequently written on preprinted DermaTran prescription pads that permitted the Roe Physicians to request multiple refill amounts, or leave it up DermaTran by marking "PRN." When given discretion,

DermaTran would frequently record 99 refills, providing patients with years of automatic refills without any physician contact.

C. The Marketing Defendants

41. Defendant **Pharmacy Marketing Services, Inc.** ("PMX") is a Georgia corporation, incorporated in August 2015 by Andy Davis with principal place of business at 210 E. 2nd Avenue, Suite 301, Rome, Georgia. Ronnie Duncan, is CEO and CFO, and his daughter Jessica Duncan serves as corporate Secretary. PMX exists primarily to perform outsourced sales and marketing for DermaTran for which it is paid a percentage of DermaTran earnings. Ronnie Duncan previously managed the PIA call center as a DermaTran employee who was "leased to PIA" and largely overseeing PIA employees, then transitioned to PIA formally in early 2013, and became CEO of PMX when PIA closed. Charles Bonano who managed DermaTran's in-house sales and marketing continues to oversee the sales and marketing team at PMX.

42. Defendant **TekSouth Corporation** is an Alabama corporation incorporated in 1983 with principal place of business in Birmingham, Alabama. TekSouth created a marketing and sales platform that facilitated the use of private patient information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104–191, 110 Stat. 1936 (Aug. 21,

1996), to be illegally utilized by sales and marketing entities in order to generate referrals for DermaTran's services. TekSouth was compensated with a portion of DermaTran's earnings ultimately receiving over $5 million dollars from the schemes.

43. Defendant **HealthLogic Partners, LLC** is a Louisiana Partnership organized in January 2016 by Louis Generes, Jourdan Generes, and Matthew Skellan with principal place of business at 8710 Glenfield Dr., Baton Rouge, Louisiana. HealthLogic Partners performed outsourced sales for DermaTran to induce physicians to refer their patients to DermaTran in exchange for a percentage of DermaTran's revenue.

44. Defendant **Titan Medical Marketing, LLC** is an Alabama LLC, formed in February 2013 by James B. Bogue with principal address at 3563 Wayside Road, Kingston, Georgia. Titan Medical Marketing performed outsourced sales for DermaTran to induce physicians to refer their patients to DermaTran in exchange for a percentage of DermaTran's revenue. Titan Medical Marketing was also used as a conduit to conceal payments made to DermaTran by Lakeside Pharmacy, as described below.

45. Defendants **Roe Third-Party Marketers** are co-conspirators located throughout the country that performed outsourced sales for DermaTran to induce

physicians to refer their patients to DermaTran in exchange for a percentage of DermaTran's revenue.

D. The Pharmacy Defendants

46. Defendant **Lakeside Pharmacy of Alabama, Inc.** ("Lakeside Pharmacy") is an Alabama corporation, incorporated in 2013 by Heather E. Ward with principal address at 17054 Highway 431, Wedowee, Alabama. After DermaTran's provider agreement was terminated by Express Scripts and other PBMs, DermaTran transferred its prescriptions to Lakeside Pharmacy, which paid DermaTran a portion of the revenue received.

47. Defendant **Legends Pharmacy, LLC** ("Legends Pharmacy") is a Texas LLC with principal place of business at 6601 Blanco Road, San Antonio Texas. After DermaTran's provider agreement was terminated by Express Scripts and other PBMs, DermaTran also transferred its prescriptions to Legends Pharmacy, which paid DermaTran a portion of the revenue received.

48. Defendant **Triad Rx, Inc.** is an Alabama corporation, incorporated in January 2012 by Matt L. McDonald, with registered address at 26258 Pollard Road, Daphne, Alabama. After DermaTran's provider agreement was terminated by Express Scripts and other PBMs, DermaTran also transferred its prescriptions to Triad Rx, which paid DermaTran a portion of the revenue received.

49. Defendant **Custom Pharmacy Solutions, LLC** is an Alabama LLC, formed by Edward H. Kuckens in January 2007, with principal address at 1821 27th Street South, Homewood, Alabama. After DermaTran's provider agreement was terminated by Express Scripts and other PBMs, DermaTran also transferred its prescriptions to Custom Pharmacy Solutions, which paid DermaTran a portion of the revenue received.

50. Defendants **Roe Pharmacies** are co-conspirators located throughout the country that received prescription referrals from DermaTran and paid DermaTran a portion of the revenue received.

E. Marketing Client Defendants

51. Defendant **Sircle Laboratories, LLC** is a Delaware limited liability company with principal office located in Madison, Mississippi. Sircle Laboratories entered into a contract with DermaTran to induce physicians to prescribe its opioid medication Xylon 10 and agreed to pay DermaTran a commission based on the volume of the resulting sales of Xylon 10.

52. Defendant **Iverson Genetic Diagnostics, Inc.** is a Nevada corporation formed in March 2007 with principal place of business located at 401 Terry Avenue, North, Seattle, Washington. Iverson Genetic Diagnostics entered into a contract with DermaTran to induce physicians and patients to prescribe and

purchase its genetic lab testing products and services and agreed to pay DermaTran based on the volume of the resulting sales of those products and services.

53. Defendant **Thayer Intellectual Property, Inc.** is a California corporation, incorporated in August 2009 by Evan Ng with principal place of business at 3650 Mt. Diablo Boulevard, Lafayette, California. Thayer Intellectual Property entered into a contract with DermaTran to induce physicians and other health care providers to prescribe its surgical devices and agreed to pay DermaTran based on the volume of the resulting sales of those devices.

54. Defendants **Roe Medical Marketing Clients** are co-conspirators located throughout the country that agreed to have DermaTran induce physicians to prescribe medications, or to purchase medical devices, products, and services, and further agreed to pay DermaTran based on the volume of the resulting sales of such medications, medical devices, products and services.

IV. APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS

A. The Anti-Kickback Laws of the United States

55. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute" or "AKS"), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1972 and has been amended many times since. The Anti-Kickback Statute arose out of Congressional concern that payoffs to those who can

influence health care decisions corrupt medical decision-making and can result in goods and services being provided that are medically inappropriate, unduly costly, medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of government health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

56. The Anti-Kickback Statute prohibits any person or entity from making or accepting "any remuneration" to induce or reward any person for, *inter alia*, referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute's prohibition applies to both sides of an impermissible kickback relationship (i.e., the giver and the recipient of the kickback). By its terms, the statute prohibits kickbacks to those who themselves make referrals and purchases as well as those who recommend that others make referrals or purchases and those who arrange those referrals and purchases. Thus the AKS extends to arrangements with marketing and sales entities. *See U.S. Dep't of Health and Human Services Office of Inspector General* ("HHS-OIG"), *Advisory Opinion 98-10* (Aug. 31, 1998) ("any compensation arrangement between a Seller and an

independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute.").

57. Underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991), broadly define the term "remuneration" as "anything of value in any form or manner whatsoever." *See* HHS-OIG, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 66 Fed. Reg. 23731, 23734 (May 5, 2003); *accord United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *7 (S.D. Ohio Dec. 18, 2008).

58. Violations of the federal AKS can subject the perpetrator to liability under the federal FCA, for example, for causing the submission of false or fraudulent claims or for making a false or fraudulent statement or record material to a false or fraudulent claim. Accordingly, claims for reimbursement for services that result from kickbacks are rendered false or fraudulent under the False Claims Act. 42 U.S.C. § 1320a-7b(g). *See also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 379-80 (1st Cir. 2011) (Medicare and Anti-Kickback Act).

59. The Anti-Kickback Statute contains safe harbors that exempt certain transactions from its prohibitions. *See* 42 C.F.R. § 1001.952. Once the Government has demonstrated each element of a violation of the Anti-Kickback Statute, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by such a safe harbor or exception. The Government need not prove as part of its affirmative case that defendant's conduct at issue does not fit within a safe harbor.

60. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. § 1320a-7(b)(7); § 1320a-7a(a)(7).

61. In addition to the AKS, the Civilian Health and Medical Program of the United States (now known as "TRICARE"), see *infra* at ¶ 76, prohibits arrangements by providers "which appear to be designed primarily to overcharge" TRICARE, including commissions and kickbacks. *See* TRICARE regulations on fraud and abuse at 32 C.F.R. § 199.9(c)(12).

B. The Federal Stark Statute and TRICARE Conflict of Interest Laws

62. Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark

Statute," prohibits a physician from making referrals for certain designated health services ("DHS"), including outpatient prescription drugs, payable by Medicare or Medicaid to an entity with which the physician has a financial relationship, unless an exception applies.

63. In enacting the statute, Congress found that improper financial relationships between physicians and entities to which they refer patients can compromise the physician's professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied on various academic studies consistently showing that physicians who had financial relationships with medical service providers used more of those providers' services than similarly situated physicians who did not have such relationships. The statute was designed specifically to reduce the loss suffered by the Medicare Program due to such increased questionable utilization of services, but Stark also applies to Medicaid claims. *See generally United States v. Rogan*, 459 F. Supp. 2d 692, 722-23 (N.D. Ill. 2006).

64. Under the Stark Statute a physician is prohibited from making referrals to an entity with which he or she has a financial relationship for designated health services payable by Medicare or Medicaid. In addition, providers may not bill Medicare or Medicaid for designated health services

furnished as a result of a prohibited referral, and no payment may be made by the Medicare or Medicaid programs for designated health services provided in violation of 42 U.S.C. § 1395nn(a)(1). *See* 42 U.S.C. §§ 1395nn(g)(1), 1396b(s).

65. Finally, if a person collects payments billed in violation of 42 U.S.C. § 1395nn(a)(1), that person must refund those payments on a "timely basis," defined by regulation not to exceed 60 days. *See* 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d); 42 C.F.R. § 1003.101.

66. The Stark Statute broadly defines prohibited financial relationships to include a direct or indirect "ownership or investment interest in the entity" or a direct or indirect "compensation arrangement," i.e., any remuneration between a physician and an entity. *See generally* 42 C.F.R. § 411.354 (a)(1).

67. "Compensation arrangements" consist of any remuneration between a physician and an entity. 42 C.F.R. § 411.354 (c). Like ownership interests, compensation arrangements can be direct or indirect. A direct compensation arrangement exists if there is no intervening person between the physician and the entity providing, for example, a lab test. An indirect relationship exists if there is an unbroken chain of persons or entities that have financial relationships (either an ownership or investment interest or a compensation arrangement), between the referring physician and the entity conducting the tests, if the referring physicians

receives compensation varying with volume or value of referrals, and if the entity furnishing the lab test has actual knowledge, or acts in reckless disregard or deliberate ignorance, of the fact that the referring physician is receiving compensation varying with the volume or value of referrals. 42 C.F.R. § 411.354(b)(5), (c)(2).

68. Once the government has demonstrated each element of a violation of the Stark Statute, the burden shifts to the defendant to establish that defendant's conduct at issue was exempted from the Stark Statute, *i.e.,* was protected by a Safe Harbor.

69. In order to qualify for any of the Stark Statute's exceptions for compensation arrangements, the compensation may not take into consideration the volume or value of referrals or other business generated by the referring physician, the agreement must be in writing, and the agreement cannot violate the Anti-Kickback Statute. *See, e.g.*, 42 C.F.R. § 411.357(p).

70. Violations of the Stark Statute may subject the physician and the billing entity to exclusion from participation in Government Health Care Programs and various financial penalties, including: (a) a civil money penalty of up to $15,000 for each service included in a claim for which the entity knew or should have known that the payment should not be made; and (b) an assessment of three

times the amount claimed for a service rendered pursuant to a referral the entity knows or should have known was prohibited. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

71. TRICARE, described *infra* at ¶ 76, will likewise deny any claim where an individual contracted to the United States Government has the "apparent or actual opportunity to exert, directly or indirectly, any influence on the referral of [TRICARE] beneficiaries to himself/herself or others with some potential for personal gain or the appearance of impropriety." 32 C.F.R. § 199.9(d)(1). Claims subject to "conflict of interest" in this way will be denied. 32 C.F.R. § 199.9(d)(2). For ease of reference, the Stark Statute and the TRICARE regulations will be referred to as "Stark Laws" or "self-referral laws" in this Complaint.

C. Government Health Insurance Programs

72. The Health Insurance for the Aged and Disabled Program, known as Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare"), is a health insurance program administered by the United States Government and funded by taxpayer revenue. The United States Department of Health and Human Services ("HHS"), through its Centers for Medicare and Medicaid Services ("CMS"), oversees Medicare.

73. Medicare was designed to be a health insurance program and to provide for payment of, among other things, medical services and equipment to persons over 65 years of age and certain others who qualify under Medicare's terms and conditions. The Medicare program has four parts: Part A, Part B, Part C, and Part D. Medicare Part A, Hospital Insurance Benefits for Aged and Disabled, covers the cost of inpatient hospital services and post-hospital nursing facility care. *See* 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B, the Supplemental Medical Insurance Benefits for the Aged and Disabled, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

74. The Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid"), is a health insurance program administered by the United States Government and the States and is funded jointly by state and federal taxpayer revenue. CMS and HHS oversee Medicaid jointly with agencies in each State.

75. Medicaid is designed to assist participating States in providing medical services, medical equipment, and prescription drugs to needy individuals. The States and the United States share reimbursement costs. States directly pay providers, and then obtain the federal contribution from accounts drawn on the United States Treasury. 42 C.F.R. §§ 430.0-*et seq*. Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, copayments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary Program, 42 U.S.C. § 1396d(p)(1), the Specified Low-Income Medicare Beneficiary Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals Program, 42 U.S.C. § 1396d(s). Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (e.g., with Medicare or private insurance providing primary coverage). Medicaid sets forth minimum requirements for state Medicaid programs to meet to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program. Medicaid sets forth minimum requirements for state Medicaid programs to meet to

qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

76. The Civilian Health and Medical Program of the United States (now known as "TRICARE"), 10 U.S.C. §§ 1071-1110, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. CHAMPVA, administered by the United States Department of Veterans Affairs ("VA"), is a health care program for the families of veterans with 100-percent service-connected disability, or for those who died from a VA-rated-service-connected disability.

77. TRICARE provides coverage for certain prescription drugs, including certain compounded drugs, which are medically necessary and prescribed by a licensed physician. Express Scripts, Inc. (Express Scripts) administers TRICARE's prescription drug benefits.

78. The Federal Employee Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other things, medical devices and surgeries for its beneficiaries. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government. As a result, fraud on

a patient covered by the FEHBP constitutes fraud on the federal government and the loss of federal funds.

79. The federal government operates hospitals, including through its Departments of Defense and VA, and receives and uses federal funds to provide medication to patients treated at these facilities and otherwise, as well as outpatient services. A network of already established VA hospitals and services make up the VA health care system.

80. The Office of Workers' Compensation Programs ("OWCP") of the U.S. Department of Labor ("DOL") administers federal workers' compensation programs under four statutes: (1) the Federal Employees' Compensation Act ("FECA"), 5 U.S.C. §§ 8101, *et seq.*; (2) the Longshore and Harbor Workers' Compensation Act ("LHWCA"), 33 U.S.C. §§ 901, *et seq.*; (3) the Federal Black Lung Benefits Act ("FBLBA"), 30 U.S.C. §§ 901, *et seq.*; and (4) the Energy Employees Occupational Illness Compensation Program Act ("EEOIC") (also known as the "Beryllium Exposure Compensation Act"), 42 U.S.C. §§ 7384, *et seq.*

81. The largest of these workers' compensation programs is the FECA program, which provides coverage for approximately three million federal and postal workers for employment-related injuries and occupational diseases. Under

the provisions of FECA, OWCP authorizes payment for medical services, including compounded prescription drugs, and establishes limits on the maximum payment for such services.

82. Together, the programs described above, and any other government-funded health care programs, are referred to as "Government Health Care Programs."

D. Goods and Services Must Be Medically Necessary and Performed Economically

83. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic reimbursement requirement under Medicare, Medicaid, and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (Medicare does not cover items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."); 5 U.S.C. § 8902(n)(1)(A) (FEHBP will not cover any treatment or surgery that is not medically necessary); 32 C.F.R. § 199.6(a)(5)(TRICARE provider has an obligation to provide services and supplies at only the appropriate level and "only when and to the extent medically necessary."); 42 C.F.R. §§ 411.15(k)(1), 411.406; *Moore ex rel. Moore v. Reese*,

637 F.3d 1220, 1232 (11th Cir. 2011) ("Although the standard of 'medical necessity' is not explicitly denoted in the Medicaid Act, it has become a judicially accepted component of the federal legislative scheme."); *United States v. Rutgard*, 116 F.3d 1270, 1275-76 (9th Cir. 1997) (holding that TRICARE and the Railroad Retirement Health Insurance Program follow the same rules and regulations as Medicare, citing, *e.g.*, 32 C.F.R. § 199.4(a)(1)(i)).

84. Health care providers must certify that services or items ordered or provided to patients will be provided "economically and only when, and to the extent, medically necessary" and "will be of a quality which meets professionally recognized standards of health care" and "will be supported by evidence of medical necessity and quality." 42 U.S.C. § 1320c-5(a)(1)-(3); *see also* 32 C.F.R. § 199.6(a)(5) (TRICARE services and supplies must "meet[] professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care").

85. These requirements prohibit defendants from manipulating billing procedures in "an intentionally wasteful manner" that maximizes their own economic benefit while providing no patient benefit. *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000).

Thus, "while there is no requirement that the least costly alternative treatment be used," requests for payment become false when they are the result of "policies to artificially (i.e., unreasonably and unnecessarily) increase the quantity of items and amount of services provided to their patients without regard to medical necessity." *United States ex rel. Vainer v. Davita, Inc.*, No. 1:07-CV-2509-CAP, 2012 WL 12832381, at *6 (N.D. Ga. Mar. 2, 2012).

86. Medicare Part D regulations also require Part D Sponsors to have "*consistent rules* for beneficiary payment liabilities" for compounded drug ingredients that are covered under Part D as well as for ingredients that are not. 42 C.F.R § 423.120(d)(2) (emphasis added). The Part D sponsor must impose those requirements on downstream entities like pharmacies by contract under 42 C.F.R. § 423.505(i)(3)(iii). Therefore, if a pharmacy calculates prices for compounded drugs using inconsistent rules or via ad hoc manipulation, it violates Medicare Part D regulations. Other Medicare guidance notes that the "least costly alternative" must be used when pricing medications. CMS, Medicare Claims Processing Manual, Ch. 17 (Aug 26, 2016) § 20.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf

87. Providers who wish to be eligible to obtain Medicare reimbursement must certify, *inter alia*, that they agree to comply with the Medicare laws,

regulations and program instructions that apply to them, and that they acknowledge, *inter alia*, that payment of claims by Medicare is conditioned upon the claim and the underlying transaction complying with all applicable laws, including without limitation, the federal AKS and the Stark Statute. *See, e.g.*, Form CMS-855A (for institutional providers); Form CMS-855S, at 24 (for certain suppliers); Form CMS-855I (for physicians and non-physician practitioners).

88. In order to be reimbursed under Medicare Part D, pharmacies must sign subcontracts with the Part D plan sponsors under contracts that "must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions," which "unquestionably" includes the AKS. 42 C.F.R. § 423.505(i)(4)(iv); *United States ex rel. Kester v Novartis Pharmaceuticals Corp.*, 41 F. Supp. 3d 323, 337 (S.D.N.Y. 2014).

89. TRICARE beneficiaries can fill prescriptions through military pharmacies, TRICARE's home delivery program, network pharmacies, and non-network pharmacies. If a beneficiary chose a network pharmacy, the pharmacy would collect any applicable copayment from the beneficiary, dispense the drug to the beneficiary, and submit a claim for reimbursement to Express Scripts, which would in turn adjudicate the claim and reimburse the pharmacy. To become a network pharmacy, a pharmacy agrees to be bound by, and comply with, all

applicable State and Federal laws, specifically including those addressing fraud, waste, and abuse.

90. Claims submitted by health care providers to Government Health Care Programs contain similar representations and certifications. *See, e.g.*, Forms CMS-1500 (paper provider claim form used for Medicare, Medicaid, TRICARE, FEHBP and OWCP); 837P (electronic version of form 1500); 1450 (UB04 – institutional provider paper claim form used for Medicare and Medicaid); 837I (electronic version of form 1450). When submitting a claim for payment, a provider does so subject to and under the terms of his certification to the United States that the services were delivered in accordance with federal law, including, for example, the relevant Government Health Care Program laws and regulations. Government Health Care Programs require compliance with these certifications as a material condition of payment, and claims that violate these certifications are false or fraudulent claims under the False Claims Act. CMS, its fiscal agents, and relevant State health agencies will not pay claims for medically unnecessary services or claims for services provided in violation of relevant state or federal laws.

E. FDA Law, Compounding Pharmacies & Drug Pricing

91. The Federal Food, Drug and Cosmetic Act ("FFDCA") prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food

and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) & (d). An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or off-label uses, except under certain narrowly construed exceptions (described below).

92. Whether a drug is FDA-approved for a particular use is a key and determining factor in whether a prescription of the drug is reimbursed under Government Health Care Programs. For example, reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10)(A). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* §1396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food, Drug, and Cosmetic Act" or which is included in a specified drug compendia. *Id.* §1396r-8(k)(6).

93. The FFDCA makes "misbranding" and the "introduction into interstate commerce" of a misbranded drug illegal. 21 U.S.C. § 331(a) & (b). A drug is misbranded if any of 26 statutory conditions are met, including as relevant

here that, "[a] drug . . . shall be deemed to be misbranded . . . [u]nless its labeling bears . . . adequate directions for use." 21 U.S.C. § 352(f)(1).

94. The FDA defines the phrase "adequate directions for use" to mean, "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. For prescription drugs, the "layman" standard is superseded by specific regulation requiring that the "[l]abeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented." 21 C.F.R. § 201.100(c)(1) (defining labeling adequate to satisfy 21 U.S.C § 352(f) for prescription drugs); *see United States v. Evers*, 643 F.2d 1043, 1051 (5th Cir. 1981).

95. The intended purpose of a drug (for which the label must be adequate), "refer[s] to the objective intent of the persons legally responsible for the labeling of [the] drugs." 21 C.F.R. § 201.128 (defining "intended uses" and related language). Evidence of "objective intent" may be shown by, "labeling claims,

advertising matter, *or oral or written statements by such persons or their representatives*." *Id.* (emphasis added). Additionally, the objective intent of the persons legally responsible for labeling the drug may be shown by, "the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* Courts have agreed that the off-label use of a drug lacks "adequate information for use" in the label, and thus the intent for a drug to be put to off-label use is sufficient to support a misbranding criminal conviction. *See, e.g., United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012) ("The government has repeatedly prosecuted—and obtained convictions against—pharmaceutical companies and their representatives for misbranding based on their off-label promotion.").

96. "Compounding" is a practice by which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or multiple drugs to create a drug tailored to the needs of an individual patient.

97. Compounded drugs may be prescribed by a physician when an FDA-approved drug does not meet the health needs of a particular patient. For example,

if a patient is allergic to a specific ingredient in an FDA-approved medication, such as a dye or a preservative, a compounded drug can be prepared excluding the substance that triggers the allergic reaction. Compounded drugs may also be prescribed when a patient cannot consume a medication by traditional means, such as an elderly patient or child who cannot swallow an FDA-approved pill and needs the drug in a liquid form that is not otherwise available.

98. The FDA does not verify the safety, potency, effectiveness, or manufacturing quality of compounded drugs. The practice of compounding is generally regulated at the state level, usually by state boards of Pharmacy.

99. However, a 2013 congressional report found that "State boards of pharmacy generally do not know which pharmacies engage in compounding, do not know whether pharmacies ship compounded drugs across state lines, and do not know which pharmacies manufacture large quantities of compounded drugs. In many cases, states are incapable of even providing accurate information regarding the numbers of registered pharmacies in their states." *See* Office of Congressman Edward J. Markey, *State of Disarray, How States' Inability to Oversee Compounding Pharmacies Puts Public Health at Risk*, 3 (April 15, 2013) https://www.markey.senate.gov/imo/media/doc/State%20Of%20Disarray%20Compounding%20Report.pdf.

100. In 1997, Congress sought to better regulate the practice of pharmacy compounding in the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. No. 105-115 (1997). The Act added a Section 503A to the FFDCA, exempting compounded drugs from, *inter alia*, the requirements to apply for a new drug approval and follow good manufacturing practices, as long as the pharmacy was licensed in a state, made the drug pursuant to a valid prescription for an individual patient, made the drug using approved ingredients and endorsed standard compounding processes, did not compound inordinate amounts or copies of commercially available drugs, and did not engage in advertising or promotion. 21 U.S.C. § 353a.[1]

101. In 2013, as a result of further abuses of the system, Congress passed the Drug Quality and Security Act ("DQSA"). This bill reformed § 503A of the FFDCA to remove the speech provisions found unconstitutional, and created a new § 503B covering compounding pharmacies that operated as "outsourcing facilities." These outsourcing facilities were exempted from FDA approval requirements and usage labeling requirements, but not from the requirements of

[1] The Supreme Court struck down the advertising prohibitions as unconstitutional restrictions on speech. *See Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). *See also* FDA, *Pharmacy Compounding Compliance Policy Guide*, § 460.200, 67 Fed. Reg. 39,409 (June 7, 2002).

good manufacturing processes, and would be subject to heightened inspection and reporting requirements.

102. The DQSA also clarified that to maintain an exemption under § 503A, the drug products must be, *inter alia*:

a. "compounded for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient"; and,

b. compounded by a licensed pharmacist in a licensed facility or by a licensed physician; or,

c. compounded in response to an actual prescription or in limited anticipatory quantities; and,

d. compounded from approved ingredients, or from ingredients that meet defined standards or that are on an FDA-published list; and,

e. not essentially a copy of commercially available drug products.

21 U.S.C. § 353a.

103. If a compounder does not satisfy exemption requirements under § 503A, and elects not to register under § 503B, the compounder is subject to the full panoply of FFDCA requirements applicable to conventional manufacturers,

including the requirements that a new drug be approved by the FDA and the prohibition on "misbranding" and "off label promotion."

104. The active ingredient or ingredients in a compounded drug may be one or more FDA-approved products, or may be bulk drug substances. Bulk drug substances—usually raw powders—are generally not approved by FDA for marketing in the United States and not covered by many Government Health Programs including Medicare Part D.

105. Active ingredients used to make a compounded drug—including bulk drug substances—are generally assigned national drug codes (NDC). NDCs are the universal product identifiers for drugs for human use. NDCs for FDA-approved products and bulk drug substances along with pricing information are published in national drug compendia. A single FDA approved product or bulk substance may be distributed by multiple manufacturers, in different forms or strengths, and by varying package sizes and, hence, may have multiple NDCs associated with it. A compounding pharmacy calculates its maximum reimbursement price based upon the published price of the constituent ingredients. The National Council for Prescription Drug Programs (NCPDP) provides a system for submitting claims called version D.0, which requires pharmacies to submit each ingredient's NDC, quantity in the final product, and price, to Government Health Care Programs.

106. Under Medicare Part D, reimbursement is based on prices for each ingredient that are negotiated between the pharmacy or its PBM and each Part D plan and hence may differ among Part D plans. The negotiated prices are based on various published listings of the ingredients' price, such as the Average Wholesale Price ("AWP"), or Medicare's maximum allowable cost, published by CMS. OWCP likewise reimburses compounded medications through NCPDP claims based on each ingredient's cost. Medicare Part B reimburses compounded drugs based on the pharmacy invoice, which Medicare contractors typically review manually. TRICARE reimburses for each ingredient of a compound medication at the lesser of the charge a pharmacy bills for, or 95% of AWP for each NDC in the compound. All these programs impose the same standards of medical necessity on drug compounding and compound drug pricing as described above. *See supra* Section IV.D.

F. The Federal False Claims Act

107. The Federal FCA creates liability for "any person who," among other things:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

c. "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

d. "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

108. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461 note, increased the civil penalty.

109. The FCA provides that "the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

110. The FCA provides that "the term 'claim' – (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

111. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship,

from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). Moreover, in the health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment…is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of…60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), amending § 1128(J(d) of the Social Security Act. *See also* 42 U.S.C. § 1320a-7k(d).

112. The FCA provides that "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

V. FACTS AND ALLEGATIONS

A. Summary of Defendants' Unlawful Conduct

113. Defendants have engaged in ongoing schemes to defraud Government Health Care Programs, most notably TRICARE, Medicaid, Medicare Part D, and FECA, since at least 2012. Their scheme to defraud consists of several interrelated frauds designed to illegally induce physicians to prescribe Defendants' products

and then manipulate their pricing to maximize the amount reimbursed by Government Health Programs and minimize the costs to patients thereby inducing overutilization. In addition, Defendants, their employees, and co-conspirators misrepresent both the safety and efficacy of their drugs and their own business practices so as to maintain their eligibility for Government Health Care Program reimbursement. When these misrepresentations are discovered, Defendants route prescriptions through third-party co-conspirators to obscure their true source.

114. These schemes violate a host of material rules and regulations rendering all resulting claims false or fraudulent under the FCA. Defendants: (a) illegally induce referrals to DermaTran through violations of anti-kickback laws and Stark Laws by offering bribes to physicians, third parties, and patients; (b) once they have secured a stream of prescription refills, Defendants illegally manipulate their prices and in some cases the prescriptions themselves to maximize the cost to Government Health Programs in violation of the bedrock rules that providers not bill goods or services simply because they are more lucrative; (c) throughout these schemes Defendants make serial false representations to the Government, physicians, and patients to secure these revenue streams, including falsely representing their business practices to Government PBMs, surreptitiously transferring prescriptions to other pharmacies to avoid government oversight, and

making misleading statements and misrepresentations to physicians and patients about the safety and efficacy of their compounds. These actions not only violate the underlying statutes and regulations that Defendants misrepresent compliance with, but independently render the resulting claims false and/or fraudulent under the federal FCA.

115. Through these schemes, which are detailed further below, Defendants have defrauded the United States and the states of tens of millions of dollars and the fraud is ongoing. In the process, the Defendants have unjustly enriched themselves.

B. Background

116. The DermaTran story has its genesis in an earlier compound pharmacy-related health care fraud in Alabama. In late 2010 Art Moss and Tim Aaron founded an Alabama pharmacy called Franklin Pharmacy (also known as Optimal Pain Control or "OPC"). In January 2011, Aaron executed agreements transferring 22% of the interest in Franklin Pharmacy each to Deborah Moss (Art Moss's wife), Robert Gussenhoven, and Sam R. Moss.[2] Complaint, *Alexander v. Aaron, et al.*, No. 3:15-cv-01314 (N.D. Ala. Aug 5, 2016).

[2] Sam and Art Moss are close relatives. Relator understands that they are brothers.

117. Deb Moss never executed her admission agreement and didn't take her shares. Rather, she appeared to be a straw for Art, who attended member meetings and took her ownership distributions. This stratagem was employed because Art was barred from having an ownership interest in a pharmacy due to prior federal convictions.

118. Franklin experienced extraordinary success within the first month of opening. By January 2012, Franklin was filling, on average, 433 prescriptions *per day*—compared to 20 prescriptions per day for a typical compounding pharmacy—and had increased its total number of employees almost tenfold, from 15 to 140. Over the course of 2012, Franklin continued to grow and at one point was the largest compounding pharmacy in the United States, filling more than 950 prescriptions on a daily basis and employing more than 200 people. During this time, Franklin recognized earnings in the millions of dollars.

119. "Effective December 31, 2011," Sam Moss and Gussenhoven entered an agreement with the Franklin Pharmacy that it would repurchase their shares for $3.8 million. They received $500,000 at closing, but the Franklin Pharmacy never paid the rest, and the two ended up being creditors at the Franklin Bankruptcy.

120. That June, Franklin suppliers were served subpoenas, and in August, officials executed a search warrant on Franklin itself. It ceased operations and

never reopened. The insiders spent $3 million on legal defense for themselves and another $1.5 million for the company, even though it was defunct at that point. They also paid themselves another $1.5 million from corporate assets.

121. Aaron, with Art and Deb Moss, attempted to reopen in Florida under the name Franklin Pharmacy South, but the business failed almost immediately. Wes Moss and Cary Moss (Art and Deb's children) then opened Florida Pharmacy Solutions, Inc. along with some other Franklin employees, and in Franklin's bankruptcy proceedings were sued for stealing Franklin assets to start it up.

122. Meanwhile, Sam Moss and Gussenhoven were looking for their next venture. They were also under investigation by the authorities still investigating Franklin Pharmacy. They met Yancey, who as CEO and Board Chair of State Mutual, had access to significant financial resources and a willingness to utilize corporate assets for his own personal investments. Yancey would serve as the "bank" for their scheme.

123. Yancey funded Moss and Gussenhoven's legal defense in the Franklin matter and, in January 2012, the three set up Transdermal Health Solutions, LLC

and Pharmacy Insurance Administrators, LLC to facilitate their scheme. Three weeks later, Transdermal's name was changed to DermaTran Health Solutions.[3]

124. The Individual Defendants recognized a weakness that they could exploit in the reimbursement policies of some government programs, particularly TRICARE and OWCP. Those policies permitted reimbursement for compounded drugs containing non-FDA approved active ingredients (known as "bulk powders") and based reimbursement in part on the AWP of those bulk powders. In 2013, "compounded drug prescriptions containing at least 1 bulk drug substance accounted for about 98 percent" of the TRICARE spending on compounded drugs and the "average cost of a compounded drug that included at least 1 bulk drug substance was $557 per prescription compared to an average cost of $53 per prescription for a compounded drug that contained only FDA-approved products." *See* United States Government Accountability Office ("GAO"), *Compounded Drugs: TRICARE's Payment Practices Should Be More Consistent with Regulations*, 16 (October 2014), http://www.gao.gov/assets/670/666339.pdf. The

[3] Gussenhoven, and Moss were previously owners of Transdermal Therapeutics, Inc. of Homewood, Alabama. They claimed that they sold their interests in that company in 2012. Transdermal Therapeutics, Inc. is still open and has also been accused by the FDA of violating good manufacturing procedures. *See* https://www.fda.gov/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm414755.pdf.

twenty-five highest-cost of these drugs, all of which were topical pain creams and gels, had an average cost ranging from about $900 to nearly $10,000. *Id.*

125. Defense Health Agency ("DHA") officials attributed the high cost of these drugs to "several factors, including the number of these substances used in each prescription, the aggressive marketing of compounded drugs containing these substances to providers, and the high AWP of these substances—which, according to DHA and Express Scripts officials, have been inflated by manufacturers of these substances. For example, according to Express Scripts, the AWP of bulk gabapentin increased by as much as 4,948 percent from 2011 to 2014, while the AWPs of bulk ketamine and bulk baclofen increased by as much as 1,313 percent and 1,102 percent, respectively, over the same period." *Id.* at 17.

126. The Individual Defendants were not the only ones in the industry to recognize the opportunities for self-enrichment. TRICARE typically spent $100 million annually on compound drug reimbursements. However, in 2013 this spend dramatically spiked, largely due to topical pain creams. By 2014, that figure had grown to $1.4 billion of which Jason Mehta, the Assistant United States Attorney overseeing these cases in the Middle District of Florida, estimated that 95 percent was fraud. Melissa Ross, FloridaPolitics.com, *More Prosecutions, Arrests Coming in Florida Pharmacy Fraud Scam* (Nov. 25, 2015),

http://floridapolitics.com/archives/195412-prosecutions-arrests-coming-in-florida-pharmacy-fraud-scam.

127. Moss recognized the transient nature of the scam and expected that this opportunity would last for only a few years. Furthermore, while some compounding pharmacies were charging $10,000 – $20,000 per prescription, Yancey consciously decided to cap the cost of their compounds at several thousand dollars per prescription to avoid government scrutiny for as long as possible. Similarly, after the nationwide alarm over the deaths caused by injections prepared by the New England Compounding Center, Individual Defendants concluded that they should avoid preparing sterile compounded preparations.

128. Between 2009 and the end of 2012, Yancey caused State Mutual to extend over $10 million in credit to Gulfcoast, a subsidiary he controlled, and utilized that credit facility to invest in startup companies in which he would stand to personally benefit. Gulfcoast ultimately lent DermaTran over $6 million.

129. DermaTran also obtained a $6.3 million-dollar mortgage from Southern Highlands Mortgage Company, another subsidiary partly owned by State Mutual. DermaTran used that mortgage to purchase State Mutual's former headquarters to use as its own principal office. That sale enabled DermaTran to qualify for a local payment in lieu of taxes program under which DermaTran was

granted a multi-year exemption from local taxes. Ultimately, State Mutual was forced to take the DermaTran mortgage onto its own books and DermaTran "sold" the headquarters back to State Mutual subsidiary (and Gulfcoast parent) Life and Health Holdings, Inc.

130. Yancey also assigned employees of State Mutual and its subsidiaries, in particular PIA, to spend all or part of their time in service of DermaTran while remaining on the books of their original employer.

131. From 2012 through the end of 2016, Yancey surreptitiously acquired more equity in DermaTran through DIII Consulting, LLC. By September 2013 Yancey held 49% of DermaTran, and in May of 2015 Gussenhoven left DermaTran and Yancey became the majority owner with 66% as follows:

Date	Entities	Units	Percentage
1/25/2012	Robert Joseph Gussenhoven		50%
	Samuel Richard Moss		50%
9/3/2013	DIII Consulting, LLC (Yancey)	490	49.0%
	SRM Holdings, LLC (Moss)	250	25.0%
	Sam Moss,	5	.05%
	Gussenhoven Holdings LLC	250	25.0%
	Robert Gussenhoven,	5	.05%
5/1/15	DIII Consulting, LLC (Yancey)	490	65.77%
	SRM Holdings, LLC (Moss)	250	33.56%
	Sam Moss	5	.67%
1/1/17	Gave notice that as of January 1, 2017 Yancey was resigning and Moss would have full control. Was later forced to amend that notice and claim April 30, 2017 as date of departure.		

132. In May 2015, the DermaTran operating agreement was revised upon Gussenhoven's departure. That document reflected a "capital account balance" to Yancey personally of $2.5 million.

C. Defendants Use Kickbacks to Obtain Referrals

133. Defendants' scheme to defraud Government Health Care Programs begins with illegally obtaining referrals for their products through the use of kickbacks and bribes. These bribes take several forms, the most basic of which is simply paying doctors thousands of dollars to write prescriptions for DermaTran compounds. DermaTran also pays Marketing Defendants and sales staff earnings-based commissions in order to induce them to refer patients to DermaTran for

prescriptions and refills. Finally, DermaTran offers bribes to patients and physicians in the form of waived copays and free drugs in order to induce the physicians to further prescribe DermaTran products and the patients to purchase them.

134. Each of these bribery schemes is prohibited by federal law and regulations, including the Anti-Kickback Statute, and with respect to the physician payments, the Stark Statute and by TRICARE's fraud and abuse regulations.

1. Cash Bribes to Physicians

135. DermaTran pays favored physicians to write prescriptions for it. These payments usually ranging from $250 to $1,000 are described as "honoraria" or "speaker's fees," and are made as either direct payments to physicians or reimbursement of sales agent's expenses. DermaTran makes multiple payments to the same physicians which in some cases comprises over $10,000 in payments.

136. However, DermaTran has no policies or systems for tracking the alleged events that these physicians are speaking at or the circumstances of the honorarium, and no policies in place to ensure that these payments reflect the fair market value of actual services performed by the physician, which would be required to take advantage of any Stark Statute or AKS safe-harbors.

137. In actuality, the claimed reason for the payments is pretextual and in most cases fictitious. These payments reflect physician bribes to induce referrals to DermaTran.

138. Such bribes violate the Anti-Kickback Statute as they are illegal remuneration in exchange for referrals of items for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). They also constitute acts of fraud and abuse to TRICARE under 32 C.F.R. § 199.9. They are also, where applicable, referrals to DHS by physicians with financial relationships to the referred service in violation of the Stark Statute and TRICARE fraud and abuse regulations. As noted above, all claims for these services are false and/or fraudulent under the False Claims Act.

2. Paying Illegal Sales Commissions

139. DermaTran also compensates Marketing Defendants in exchange for their making efforts to procure referrals for DermaTran's products and services.

140. As explained above, the AKS makes it a criminal offense to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. 42 U.S.C. § 1320a-7b(b). For purposes of the AKS "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Under the statute,

referrals include, but are not limited to, arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made by a Federal health care program.

141. Here "remuneration" is intentionally paid to these parties to induce referrals of items or services paid for by a Federal health care program, in violation of the AKS. By its terms, the statute imposes liability on both parties on both sides of the impermissible transaction.

142. HHS-OIG has long noted that marketing and sales agreements are likely to violate the AKS, noting in the preamble to the 1991 final safe harbor rules, that the anti-kickback statute on its face prohibits offering or acceptance of remuneration, *inter alia*, for the purposes of "purchasing, leasing, ordering or arranging for any . . . service, or item paid for by Medicare or State health care programs." 56 Fed. Reg. 35952, 35952 (July 29, 1991).

143. In particular, HHS-OIG has expressed concern that percentage compensation arrangements like those here are potentially abusive, "because they provide financial incentives that may encourage overutilization of items and services and may increase program costs." *See* HHS-OIG, *Advisory Opinion 98-1* (Mar. 19, 1998). These agreements are particularly problematic where they include "significant financial incentives that increase the risk of abusive marketing and

billing practices," active marketing, including direct contacts to physicians and patients, and lack safeguards against fraud and abuse. *Id.*

144. This is not only true of third-party marketing companies, but inadequately managed independent sales agents. HHS-OIG has noted that "Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers. Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent." HHS-OIG, *Advisory Opinion 98-10* (Aug. 31, 1998).

145. While there is an AKS safe-harbor for employees, HHS-OIG has long refused to include independent contractors in this definition. The regulations interpreting the AKS specifically confine "employees" to those common-law employees as described at 26 U.S.C. § 3121(d)(2). *See* 42 C.F.R. § 1001.952(i). In the preamble to those regulations, HHS-OIG rejected requests to expand this definition to include independent contractors because "of the existence of widespread abusive practices by salespersons who are independent contractors and,

therefore, who are not under appropriate supervision and control . . . [HHS-OIG] cannot expand this provision to cover such relationships unless we can predict with reasonable certainty that they will not be abusive." 56 Fed. Reg. 35952, 35981 (July 29, 1991); *see also* HHS-OIG, *Advisory Opinion* 99-3 (Mar. 16, 1999) (noting the "longstanding concern with independent sales agency arrangements").

146. When scrutinizing particular arrangements, HHS-OIG has identified several characteristics that it calls "suspect characteristics" because they are associated with an increased potential for program abuse, particularly overutilization and excessive program costs. These include:

a. compensation based on percentage of sales;

b. direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent;

c. direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;

d. direct contact between the sales agent and Federal health care program beneficiaries;

> e. marketing of items or services that are separately reimbursable by a Federal health care program . . . whether on the basis of charges or costs.

HHS-OIG, *Advisory Opinion* 99-3 (March 16, 1999).

147. Here Defendants' arrangements all constitute prohibited remuneration to induce referrals of items or services paid for by a Federal health care program, in violation of the AKS.

a. 1099 Employees

148. Throughout most of its existence, DermaTran maintained a massive sales staff for an alleged retail pharmacy. Its sales staff comprised over 150 positions throughout the nation. All of these individuals were primarily compensated through commissions. These generally included 15% of all direct sales as well as bonuses for team performance. Sales Managers likewise received bonuses based on their own direct sales and that of their staff.

149. These commissions were massive. Multiple sales agents pocketed amounts near $1 million throughout the course of the scheme, and one agent obtained nearly $2 million. They also had all the hallmarks that HHS-OIG identifies when looking at suspect relationships: they included significant financial incentives that increase the risk of abuse; involved active marketing (including

direct contacts to physicians and patients); and lacked safeguards against fraud and abuse.

150. Nor can DermaTran claim an exemption for payments to its sales staff under the AKS employee safe harbor at 42 C.F.R. § 1001.952(i), because it treats its sales agents as either W-2 employees or 1099 independent contractors depending on their request, and frequently converts them from one to another upon request. *See* 26 U.S.C. § 3121(d)(2); 42 C.F.R. § 1001.952(i). Under OIG guidance, 1099 independent contractors are ineligible for this safe-harbor because of "widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control . . . unless [HHS-OIG] can predict with reasonable certainty that they will not be abusive." 56 Fed. Reg. 35952, 35981 (July 29, 1991).

151. DermaTran's willingness to compensate its sales staff as 1099 independent contractors in itself suggests that they are not common-law employees under 26 U.S.C. § 3121(d)(2) as required for the AKS safe-harbor. There was no distinction between the level of supervision given to those sales agents who took "independent contractor" status and those who were compensated as W-2 workers. In every case, no DermaTran employee exercised supervision and control; the sales staff had discretion over their hours and worked from home or a place of their

choosing rather than a DermaTran location. *See, e.g., Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 323-24 (1992). There was thus no basis to conclude that *any* sales agents were under "appropriate supervision and control" sufficient "to predict with reasonable certainty that they will not be abusive" as required by HHS-OIG. 56 Fed. Reg. 35952, 35981 (July 29, 1991).

152. Knowing full well that its arrangements were illegal, DermaTran purported to "carve-out" commissions paid for non-Government Health Care Programs from the government segment of its business. In Advisory Opinions addressing a variety of factual patterns and a Special Fraud Alert, HHS-OIG has warned that "[a]rrangements that 'carve out' Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business." HHS-OIG, *Special Fraud Alert: Laboratory Payments to Referring Physicians* (June 25, 2014).

153. DermaTran even permitted some sales staff to set up LLCs to operate as independent contractors performing sales services for DermaTran and being compensated for referrals.

154. Each referral induced by DermaTran's marketing and sales violated the AKS, and TRICARE fraud and abuse regulations, and subsequently constituted a false or fraudulent claim under the FCA.

b. Pharmacy Insurance Administrators

155. Pharmacy Insurance Administrators was set up to assist and manage DermaTran from within the State Mutual corporate family. It ostensibly handled "claims administration." It also served to push many DermaTran employment costs onto the State Mutual books. Yancey and other State Mutual corporate officers also took substantial salaries from PIA.

156. PIA also operated as a secondary sales force, convincing patients and their physicians to fill, refill, and renew lucrative prescriptions with DermaTran. PIA's operating agreement with DermaTran called for it to receive a percentage of DermaTran revenue.

157. PIA employees would contact patients to induce them to fill and refill their prescriptions and when necessary would contact physicians to obtain prescriptions. PIA employees made decisions on which fills and refills to pursue, primarily based on the highest revenue potential of a claim.

158. PIA sales scripts instructed employees to arrange their calls by the gross profit available for the prescription and inform patients who were concerned

about their copayments to "accept whatever they can pay and there will be no further collections." They were also instructed to enroll patients in auto-refill programs that are illegal under Government Health Programs, and when insurance reimbursements fell, to seek higher paying formulations.

159. In 2015, after government scrutiny of compounding pharmacies led to a decrease in DermaTran and consequently PIA revenue, PIA staff were told that they needed to bill $40,000 daily to survive. They were advised to "Be flexible. You may be asked to do new things. Please be willing to do whatever is needed to make us successful."

160. Each refill procured by PIA was done so in violation of the anti-kickback laws and the TRICARE fraud and abuse regulations and therefore false and/or fraudulent under the FCA.

c. HealthLogic Partners

161. HealthLogic Partners is a pharmacy marketing firm that DermaTran pays to induce physicians and patients to utilize DermaTran products.

162. HealthLogic operates similarly to DermaTran's sales force in that seeks out patients and physicians and induces them to prescribe and purchase compounded drugs. Like DermaTran, HealthLogic Partners utilizes preprinted

prescription pads and pushes particular formulations, rather than take orders from physicians.

163. The difference with HealthLogic is that it operates as a free-agent. It obtains prescriptions and commitments for orders, then looks for a compounding pharmacy that will fill the prescription. The pharmacy then sends a portion of the revenue earned back to HealthLogic in violation of the AKS and TRICARE fraud and abuse regulations.

164. HealthLogic Partners has a steady relationship with DermaTran and Moss is presently seeking to grow the volume of business. HealthLogic has its own fax line that it "passes through" to DermaTran.

165. DermaTran regularly shares extensive details from patients' medical records to facilitate HeathLogic Partners' sales activities and to track and pay commissions. This data constitutes "Protected Patient Information" under HIPAA and may not legally be transferred to facilitate sales or the payment of illegal remuneration.

166. Each prescription procured by HealthLogic Partners violated the AKS and TRICARE fraud and abuse regulations and consequently the FCA.

d. TekSouth Corporation

167. TekSouth is an IT company based in Birmingham, Alabama. The owner, Steve Wilshire, was Rob Gussenhoven's next door neighbor. Wilshire also had connections with the DOD, due to TekSouth's previous DOD work. This helped facilitate DermaTran's fraud against TRICARE.

168. TekSouth built a custom data-system internally known as the Sales Order Management System or SOMS. SOMS was key to DermaTran's schemes and comprised a number of distinct systems.

169. Data warehousing: DermaTran pharmacy software resided on three separate databases, one for each pharmacy location. SOMS combined the accounting, sales, customer service and management data of all three locations.

170. Sales Commissions: SOMS contained detailed data and calculations for determining the sales commissions payable to the third-party sales agents. This data included substantial HIPAA protected information including patient identifications, prescriptions, insurance, etc.

171. Protected Data for Marketing: Sales staff had access to the HIPAA-protected data to facilitate their ability to sell DermaTran products. There is no medical necessity for sales agents to have specific patient prescription information and it is forbidden by HIPAA. However, Defendants' sales staff found it helpful to

see which prescriptions patients had utilized. Sales staff also used the information to obtain prescription refills if the patients refused. For example, on occasion sales staff would utilize the patient information in SOMS to impersonate a patient's family member and pay the copayment themselves, thereby securing the lucrative commissions.

172. Workflow: PIA call center staff and DermaTran pharmacy staff used this system for their workflow in processing claims. Thus, Pharmacy records including ordering, processing, and compounding records were stored in SOMS.

173. Accounting: Accounting used this system to compile revenue numbers and record commissions for payroll submission.

174. Management reporting: Management used this system daily to track Key Performance Indicators such as prescriptions, billings, receivables, etc.

175. TekSouth was compensated with a percentage of DermaTran revenue. Neither TekSouth nor Wilshire had ownership in DermaTran, but Wilshire and other TekSouth staff were in attendance at all board meetings. They created the system to knowingly and blatantly violate HIPAA patient protections in order to facilitate sales and marketing activities and calculate commissions paid to sales staff.

176. TekSouth therefore was paid remuneration in return for arranging for the furnishing of or purchase of items for which payment may be made in whole or in part under a Federal health care program in violation of the AKS. Because TekSouth's compensation depended on the resulting volume of referrals, it is ineligible for any AKS safe harbor. Furthermore, this relationship had the hallmarks of a particularly problematic relationship under HHS-OIG guidance: it plainly involved abusive marketing and billing practices, facilitated active marketing with direct contact to physicians and patients, and lacked safeguards against fraud and abuse including HIPAA violations. *See* HHS-OIG, *Advisory Opinion 98-1* (Mar. 19, 1998).

177. Each prescription resulting from the use of the TekSouth's illegally procured efforts to construct the SOMS system was a violation of the AKS and the TRICARE fraud and abuse regulations and therefore false and/or fraudulent under the FCA.

e. Pharmacy Marketing Services

178. In 2015, Yancey and Moss became keenly aware that TRICARE was starting to look into compounding pharmacies. In May 2015, TRICARE cut reimbursements to compounding pharmacies – greatly reducing the profitability of Defendants' schemes. Later, the Wall Street Journal published a series of articles

about TRICARE investigations into fraud committed by Florida-based compounding pharmacies that operated fraudulent schemes similar to Defendants', suggesting that such activity would be a target of scrutiny.

179. The Individual Defendants became concerned that they were exposed to prosecution and took steps to obstruct any potential prosecution and separate Yancey and State Mutual from any fallout.

180. SOMS was shut down and likely deleted in order to destroy the evidence of Defendants' fraud.[4] Moss personally sought the means to delete information from pharmacy software related to TRICARE claims.

181. The Accounting systems were moved to servers unconnected to State Mutual, and PIA was shuttered. In 2017 Yancey curtailed the practice of having State Mutual employees perform work at DermaTran, relinquished his equity held through DIII Consulting, and resigned his formal role as CEO.

182. Pharmacy Marketing Services was created and the sales agents were moved from DermaTran to PMX, so that DermaTran could say they did not have a sales force. This entity was formally led by Ronnie Duncan and his daughter

[4] The hosting of the SOMS system had been transferred from Defendant TekSouth to Teklinks an Alabama hosting company. It is unknown whether Teklinks, TekSouth, or Defendants may possess backups of the SOMS data.

Jessica Duncan. Ronnie Duncan was formerly the president of PIA. Jessica Duncan is no longer affiliated with any of the companies but remains an officer in title.

183. Ronnie Duncan is a strong Yancey loyalist and the only one who would agree to the title. He is, however, an officer in name only; he signs whatever documents are put in front of him.

184. The purpose of PMX was to formally separate sales staff from DermaTran, which the Individual Defendants viewed as among the legal risks they faced. However, this separation exists solely on paper; all administrative, accounting, sales, and management decisions remain exactly as they were under DermaTran. In 2017, Yancey further acted to separate State Mutual employees from DermaTran.

185. Sales agent compensation remains commission based, only now DermaTran transfers funds to PMX to make those payments. This, of course, solves none of the AKS problems identified above. In fact, it simply exacerbates them.

186. PMX is now paid to, *inter alia*, induce referrals and purchases of DermaTran products. Moreover, its compensation varies in direct proportion to the amount of revenue it obtains. This plainly violates the AKS and all relevant claims are false and/or fraudulent under the FCA.

187. PMX also contracted with Defendant pharmacy, Lakeside, whose activities are described *infra* at ¶¶ 193-198, to provide marketing of compounding pharmacy services to prescribers. As with PMX's services to DermaTran, compensation was set at a percentage of net revenue, violating the AKS and the TRICARE fraud and abuse regulations. Crucial details of the arrangement, such as the nature of the services and the amounts of the compensation, were not set forth in writing or fixed in advance but only to be defined in detail in the course of the arrangement, thereby precluding the application of an AKS safe harbor.

f. Titan Medical Marketing

188. Titan Medical Marketing is a pharmaceutical and medical device marketing firm that DermaTran pays to induce physicians and patients to utilize DermaTran's products. In an effort to obscure and disguise the illegal nature of that arrangement, DermaTran executives used Pharmacy Marketing Services as the party to its distributor agreement with Titan Medical Marketing.

189. Titan Medical Marketing purported to operate from a location in Cedar Bluff, Alabama. However, Titan Medical Marketing's bank account and its President Donald Bogue were both located in Rome, Georgia. Eventually, Donald Bogue began to operate Titan Medical Marketing out of offices in Rome, Georgia owned by DermaTran and State Mutual Insurance Company.

190. Titan Medical Marketing and Donald Bogue also maintained close relationships with senior DermaTran executives including Sam Moss and Senior Vice President Charles Bonanno. Charles Bonanno is identified as one of the four members Titan Medical Marketing's "Executive Team" on its public website.

191. Titan Medical Marketing was paid to induce referrals and purchases of DermaTran products. Its compensation varied in direct proportion to the amount of referrals it induced. This activity violated the AKS and all relevant claims are false and/or fraudulent under the FCA.

192. Titan Medical Marketing was also involved in concealing Lakeside Pharmacy's payments to DermaTran. In order to conceal the improper and unlawful nature of the payments that Lakeside Pharmacy directed back to DermaTran, as described below, the payments were made in the form of checks issued from a bank account maintained in the name of Titan Medical Marketing. In internal communications and records, DermaTran personnel referred to the Titan Medical Marketing checks as "Lakeside payments."

g. Lakeside Pharmacy, Legends Pharmacy, Triad Rx and Custom Pharmacy Solutions

193. As the government began to take steps to curtail the practices at the heart of Defendants' schemes, the TRICARE PBM, Express Scripts, also began to scrutinize compound pharmacy providers.

194. As part of Express Scripts' efforts, it became aware of Defendants' copayment waiver schemes detailed below, and terminated DermaTran's Rome, Georgia pharmacy provider contract, precluding TRICARE reimbursement for DermaTran claims. CVS/Caremark and Prime Therapeutics likewise terminated DermaTran's provider agreements.

195. In response, Defendants sought to circumvent these bars by transferring prescriptions submitted to DermaTran's Rome pharmacy to other pharmacies.

196. Some prescriptions were transferred to DermaTran's Louisville location, despite the fact that it employed the same prohibited copayment practices that resulted in the termination of DermaTran's provider agreement in the first place.

197. Defendants also transferred prescriptions to Defendants Lakeside Pharmacy, Legends Pharmacy, Triad Rx, Custom Pharmacy Solutions, and Roe Pharmacies. Each of these pharmacies would fill the prescriptions sent by DermaTran and in exchange for the referral, remit a portion of the revenue earned back to DermaTran.

198. This exchange of money for prescriptions violates the AKS and the TRICARE fraud and abuse regulations and the resulting claims were false and/or fraudulent under the FCA.

h. Improper Payments to DermaTran by Marketing Client Defendants

199. In keeping with its relentless efforts to maximize profits without regard to the governing laws and regulations, DermaTran was also the recipient of improper kickback payments from the pharmaceutical manufacturer Sircle Laboratories, the genetic testing provider Iverson Genetic Diagnostics, and the medical device manufacturer Thayer Intellectual Property.

200. Sircle Laboratories entered into a contract with DermaTran to induce physicians to prescribe its opioid medication Xylon 10. DermaTran's commission payments were calculated based on the volume of the resulting sales of Xylon 10.

201. Iverson Genetic Diagnostics entered into a contract with DermaTran to induce physicians and patients to prescribe and purchase its genetic lab testing products and services. Iverson Genetic Diagnostics agreed to pay DermaTran based on the volume of the resulting sales of those products and service.

202. Thayer Intellectual Property entered into a contract with DermaTran to induce physicians and other health care providers to prescribe its Manos surgical

device. Thayer Intellectual Property agreed to pay DermaTran based on the volume of the resulting sales of those devices.

203. Each sale induced by DermaTran of the Sircle opioid Xylon 10, the Iverson genetic testing products and services, the Thayer Manos surgical device, and medical products and services produced by the Roe Medical Marketing Clients violated the AKS and TRICARE fraud and abuse regulations and consequently, violated the FCA.

3. Bribing Patients and Physicians with Waived Copayments and Free Drugs

204. Once Defendants have induced the purchase of DermaTran products through the payment of kickbacks, their focus shifts to ensuring that patients continue to bring lucrative prescriptions to DermaTran and that physicians continue to refer patients to DermaTran.

205. This is accomplished through several individual schemes that collectively ensure that copayments are not charged to patients who do not wish to pay them. In cases in which patients' insurance will not cover the expensive prescriptions, they are shifted to lower cost cash formulas or given free drugs. This operates as a bribe to both patients and their physicians.

206. Patient cost-sharing via copayments and deductibles is an integral part of the legislative scheme for Medicaid, Medicare, and TRICARE. 42 U.S.C. §

1396o-1 (permitting states to impose cost-sharing for Medicaid); 42 U.S.C. § 1395w-102 (providing for deductibles and copayments under Medicare Part D); 32 C.F.R. § 199.17(m) (describing cost-sharing for some TRICARE beneficiaries).

207. HHS-OIG notes that "[r]outine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." *See* HHS-OIG, *Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B*, 59 Fed. Reg. 65372, 65374 (Dec. 19, 1994).

208. False claims result because "[a] provider, practitioner or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge," by, for example, representing a prescription cost at $100 (supporting a government payment of $80) when failure to collect the $20 co-pay renders the actual charge $80 (supporting only a government payment of $64). *Id.* at 65375.

209. The practice of copayment and deductible waiver also results in false claims to Medicare because it distorts patient's true out-of-pocket (TrOOP) costs. These are the expenses that count toward a patient's Medicare drug plan out-of-pocket threshold. TrOOP costs determine when a person's catastrophic coverage portion of their Medicare Part D prescription drug plan will begin, at which point

their copayment falls dramatically and the Government picks up the bulk of their prescription expenses. See HHS-OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, Appx. B (Oct. 2008) (identifying problem of inappropriate manipulation of TrOOP, including "[b]eneficiary manipulated TrOOP to push through the coverage gap to reach catastrophic coverage before being eligible").

210. The AKS also explicitly enumerates the waiver of copayments and deductibles as a form of remuneration. 42 U.S.C. § 1320a-7a(i)(6). The TRICARE fraud and abuse regulations likewise specifically describe this as a form of fraud and abuse. *See* 32 C.F.R. § 199.9(b)(1) ("The types of abuse or possible abuse situations under [TRICARE] include, but are not limited, to . . . A pattern of waiver of beneficiary (patient) cost-share or deductible."); *id.* at § 199.9(c)(13) (fraud includes "agreements or arrangements between the supplier and recipient . . . that result in billings or claims which include unnecessary costs or charges to [TRICARE].").

211. While "it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. . . . In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are

medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services." HHS-OIG, *Special Fraud Alert*, 59 Fed. Reg. at 65375. Thus, routine waiver of copayments and deductibles can give rise to false claims for the payment of medically unnecessary items.

212. Thus, while providers may waive copayments and deductibles in cases of financial hardship, this exception "must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made." *Id.* The HHS-OIG notes that "routine use of 'Financial hardship' forms which state that the beneficiary is unable to pay the coinsurance/deductible (*i.e.*, there is no good faith attempt to determine the beneficiary's actual financial condition)," and refusal "to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigence (*e.g.*, a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals)" are indications of such improper waiver. *Id.*

213. The Individual Defendants viewed the waiver of copayments as a core part of their plan and from the start sought ways to do so while avoiding

government sanction. Defendants' schemes to avoid copayments took several forms. The simplest was instructions to sales people that if the patient balked at paying a copayment, they could tell the patient it would not be collected. Patient records reflected notes that the "Patient asked to be invoiced" which was code for the patient knows no attempt to collect will be made.

214. Defendants also invented a Patient Assistance Program, referred to as "PAP." This program was designed to resemble a "financial hardship" program, but it was simply a ruse. The program was used regularly, whenever patients requested, and no attempt was ever made to verify that patients were indeed indigent before they "qualified" for the program.

215. Defendants also invented a sham "study" called the Patient Experience Project referred to as "PEP." When patients complained about copayments, they were invited to take what was essentially a consumer survey; the reward for participation was an account credit of $75 that would be applied to the drug's copayment. The results of the "study" were never utilized.

216. In some cases, sales agents would pay copayments with personal credit cards because their own commission was greater than the copayment. In other cases, PIA president Ronnie Duncan would send gift cards to patients to cover copayments.

217. As part of the drug price manipulation described below, Defendants identified the cheapest formulations of compound drugs. They referred to these formulations as "Cash Formulas" or "CF" and would utilize them to charge cash-paying patients far less than the price charged to Government Health Care Programs for similar substances to induce further purchases from patients and referrals from physicians. In other cases, they would arbitrarily lower the price they charged patients for the same reason. Finally, Defendants and favored physicians agreed that when insurers would not pay for medication, it would simply be given away free.

218. For at least one of their prescriptions, Lidocaine, Defendants developed a card program along with the drug supplier, DSquared Pharmaceuticals. Defendants utilized this program to waive copayments even under Government Health Care Programs where such program use is illegal, but rarely discovered. *See* HHS OIG, *Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs* (Sept. 2014) (describing how using copayment cards with Government Health Care Programs is illegal but continues to occur even when the cards specifically warn they are not to be used with the Programs).

D. Manipulating Billing to Maximize Their Profit with No Benefit to Patients

219. As noted above, the bedrock Government Health Care Program rules require that goods and services be provided economically and only where medically necessary. Defendants violated these by employing billing procedures in "an intentionally wasteful manner" that maximized their own economic benefit while providing no patient benefit. *Kneepkins*, 115 F. Supp. 2d at 43.

220. Claims for payment resulting from "policies to artificially (i.e., unreasonably and unnecessarily) increase the quantity of items and amount of services provided to their patients without regard to medical necessity," are false under the relevant false claims acts. *See Vainer*, No. 1:07-CV-2509-CAP, 2012 WL 12832381, at *6. TRICARE also prohibits "[b]illing substantially in excess of customary or reasonable charges." 32 C.F.R. § 199.9(b)(7) and a "pattern of claims" for medically unnecessary prescriptions. 32 C.F.R. § 199.9(b)(3).

221. Defendants billed Government Health Care Programs for their products by taking the constituent drugs' and bulk drug ingredients' NDC numbers; submitting claims for reimbursement with those numbers to third party insurers, including Government Health Care Programs; observing whether the formula was accepted for reimbursement; and noting the maximum reimbursement rates.

222. Defendants' claims were false and/or fraudulent because they were the result of byzantine procedures by which Defendants identified and utilized the highest priced formulation of a given compound reimbursed by a particular insurer. Where patients were being given free drugs as kickbacks to them and their physicians, Defendants would utilize similar but cheaper formulations. In other cases, Defendants would substitute different products that were cheaper to produce, medically equivalent, and commercially available for a few dollars.

223. Defendants recognized that to obtain the maximum reimbursement possible for their products, they required the ability to charge distinct purchasers different amounts for the same prescription.

224. This was originally done arbitrarily. Defendants would prepare large batches of a compound and simply charge different amounts depending on the patient, insurance, and their whim. Thus, for example, different prescriptions bearing the same lot number, would be charged differing amounts as Defendants saw fit to maximize their profit.

225. Later, Defendants exploited a quirk in the reimbursement policies of some Government Health Care Programs, notably TRICARE, by which prescriptions were reimbursed as a function of the AWP of the bulk ingredients, each designated with a particular NDC. Defendants recognized that different NDCs

of medically similar substances carried different AWPs and therefore reimbursement rates.

226. Defendants tasked DermaTran pharmacy technicians and PIA employees with testing different combinations of ingredients and noting the reimbursement rates offered by a given insurer. The goal was to find the formulation providing the highest reimbursement allowable by an insurer to use with a patients' billing – this was known as "Testing."

227. Defendants produced extensive written procedures on these processes that made clear that selection of particular formulations was a function of the Pharmacy Cost, Marketing Cost, Copay Amount, and Insurance Pay Amount. These procedures also involved deleting the test prescriptions utilized and/or to use a new prescription number once it had been decided what to bill for to ensure there was no record of the activities.

228. These procedures also identified formulations that were utilized when patients were paying cash (referred to as CF – Cash Formula – in a patient's record) or when drugs were being provided free as a kickback to patients and their physicians in an improper attempt to avoid reporting prices as usual and customary when charging enormous amounts to Government Health Care Programs.

229. These formulas produce combinations of compounds roughly matching the same prescription that would be substituted by Defendants. Although physicians were sometimes notified as to the substitute, the "Testing" was typically done without physician consultation and Defendants then suggested substitution to the physicians. Defendants' policies made clear that the sole consideration in these substitutions was maximization of their own profit, regardless of "economy" to the government or even whether the ingredients, such as non-FDA approved powders, were permissible under program guidelines.

230. In some cases, Defendants would substitute cash formulas of their expensive products with Lidocaine - referred to as LIDO prescriptions. These consisted of only one active ingredient, Lidocaine. They were essentially identical to pain creams that could be purchased from retail drugstores for a few dollars, but Defendants' prescriptions cost several hundred dollars. While this price represented a relative bargain compared to their compounded drugs, substitutions to expensive copies of over-the-counter drugs were made on the basis of Defendants' profit, not on any assessment of medical necessity.

231. Defendants also took advantage of other quirks in government reimbursement procedures to maximize their revenue. They discovered that reimbursements for two 15-day supplies each month would provide more revenue

than one 30-day supply, and accordingly shifted their patients to 15-day supplies where possible.

232. Defendants further sought to maximize their revenue from this scheme by putting patients on auto-refill programs wherever possible.

233. Automatic refills of prescriptions, while often convenient for patients, have been identified by CMS as a source of fraud, waste, and abuse. CMS has made clear that it regards the practice of automatically refilling prescriptions without patient consent as causing medically unnecessary and hence false claims, because automatic refills end up being mailed and billed to Government Health Care Programs when they are not required by the patient, and when that happens are rarely returned and the moneys returned to the government. *See, e.g.*, CMS, 2014 Announcement, 144-45 (Apr. 1, 2013), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2014Announcement.html.

234. Defendants' auto refill patients received a new supply of the medication without any confirmation that the drug was medically necessary or that the patient needed more. Defendants employed this policy wherever possible, despite the statements by Government Health Care Programs that such policies result in claims that are not medically necessary.

235. Where physicians failed to specify a number of refills, Defendants would record the prescription with very large numbers of remaining refills, sometimes as many as 99 refills. Coupled with auto-refill, this resulted in patients receiving a prescription for over a year without any contact with their physician.

236. These claims resulted from "policies to artificially (i.e., unreasonably and unnecessarily) increase the quantity of items and amount of services provided to their patients without regard to medical necessity." *See Vainer*, No. 1:07-CV-2509-CAP, 2012 WL 12832381, at *6. They also constituted "[b]illing substantially in excess of customary or reasonable charges." 32 C.F.R. § 199.9(b)(7) and a "pattern of claims" for medically unnecessary prescriptions. 32 C.F.R. § 199.9(b)(3). All such claims are false and/or fraudulent under the FCA.

E. False and/or Fraudulent Statements

237. Finally, Defendants made a number of outright false or fraudulent statements about their products and their business model in the course of their schemes. Defendants misrepresented the safety and efficacy of their products in their marketing and sales presentations and the usual and customary price of their drugs in their claims. Defendants also misrepresented the nature of their business in their initial applications to qualify as a provider for Government Health Care

Programs, and finally misrepresented their very existence as a retail pharmacy rather than an unlicensed manufacturer of unapproved and unlabeled drugs.

1. Misrepresentations of Safety and Efficacy

238. Defendants promoted their products as an alternative to oral medication. Their website asked "If your knee hurts, why get your liver involved? The most basic benefit of topical medications is the direct application of medicine to the pain area or its trigger point." This statement, and others like it, falsely suggest that simply because a substance was topically applied, it would not be processed through the liver.

239. DermaTran's website also referred to the formulas as "non-addictive," falsely stating that "The reason for this lack of dependence is that these compounded drugs are applied topically and do not contain medicines that are addictive. Patients with drug-seeking behaviors experience none of the side effects from topically applied pain creams that they would normally expect from opiate oral pain medications."

240. Defendants' sales staff made even more egregious claims than those put in writing. In reality, all such statements were false and misleading, and posed a risk to patient safety. Any chemical that enters the blood stream in sufficient quantities has the potential to "get your liver involved." The FDA requires

extensive animal studies to understand the Pharmaco-dynamics of a compound before permitting entities to make such claims, and DermaTran lacked any support. Further, the majority of DermaTran's formulations contained Ketamine, a powerful anesthetic that is a Schedule III controlled substance because of its potential for abuse. Other formulations, including those for "migraines" and "tension headaches," included Tramadol, a powerful narcotic that has serious side-effects and the potential for addiction.

2. Misrepresentations of Usual and Customary Price

241. As part of the imperative to only reimburse costs that are expended in the most economical means possible, Government Health Care Program regulations mandate that payments for drugs under the program not exceed providers' "usual and customary charges to the general public." *See, e.g.,* 42 C.F.R. § 447.512(b) (Medicare). These regulations "should be read to ensure that where the pharmacy regularly offers a price to its cash purchasers of a particular drug, Medicare Part D receives the benefit of that deal." *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 644 (7th Cir. 2016), *cert. denied sub nom. Kmart Corp. v. U.S. ex rel. Garbe*, 137 S. Ct. 627 (2017).

242. The CMS Medicare Prescription Drug Benefit Manual has long noted that "where a pharmacy offers a lower price to its customers throughout a benefit

year," the lower price is considered the "usual and customary" price and Government Health Care Programs reimburse the pharmacy on the basis of that lower price, even if the Plan's contract with the pharmacy would allow for a higher price. Centers for Medicare & Medicaid Servs., Chapter 14—Coordination of Benefits, *in* Medicare Prescription Drug Benefit Manual 19 n.1 (2006), https://perma.cc/MW6A-H4P6.

243. Likewise, TRICARE's reimbursement manual provides that for drugs not excluding compounded drugs the "allowable cost will be the lesser of the usual and customary price or the maximum allowable cost (MAC) or . . . contractor's contracted rate for ingredient cost." TRICARE Reimbursement Manual 6010.61-M (Mar. 10, 2017) ch. 1 Section 15, § 3.2.1.

244. As described above, DermaTran established multi-faceted pricing for different insurers, but in each case the cheapest pricing was designated the cash formula or CF. That price was regularly available to its cash purchasers of that particular drug. That CF price should, therefore, have been reported as DermaTran's "usual and customary" price when submitting claims.

245. However, when DermaTran submitted claims to Government Health Care Programs, each formula had its own usual and customary price, not matching to the one reported for the cash formulas and therefore not equivalent to the price

charged to the general public. Had DermaTran reported genuine and consistent usual and customary prices, Government Health Care Programs would have become aware of DermaTran's overcharging practices and that they were being defrauded and declined to pay claims.

3. Falsely Representing Business Practices in Program Applications

246. DermaTran falsely represented its business practices when it signed its provider agreements and when it renewed them and agreed to abide by the relevant government regulations. In particular, DermaTran falsely stated that it would:

a. only waive copayments in the event of *bona fide* financial need;

b. not violate the Anti-Kickback and Stark Statutes; and

c. protect patients' information in compliance with HIPAA.

247. Each of these misrepresentations was knowingly false when DermaTran made the agreements.

248. In 2015, as part of its efforts to combat the compound pharmacy abuses of the sort perpetrated by Defendants, TRICARE PBM Express Scripts reviewed its provider relationships and discovered that DermaTran had misrepresented its policy with respect to waiving copayments and failed to disclose that it waives copayments in situations other than *bona fide* financial need.

249. Based on that misrepresentation, Express Scripts terminated DermaTran's provider agreement for the Rome, Georgia location. Caremark, PBM for several Government Health Programs also terminated its contract with DermaTran due to copay waivers and for billing for NDCs different than those used. Prime Therapeutics, likewise terminated its provider agreement for poor audit performance.

4. Misrepresentations of DermaTran as a Pharmacy Rather Than an Unlicensed Manufacturer

250. DermaTran claims to be a retail pharmacy regulated under § 503A of the FFDCA. However, as detailed above, DermaTran violates nearly all of the requirements of a retail pharmacy, both before and after the DQSA. Under the law retail pharmacies must compound drugs pursuant to a valid prescription for individual patients or in limited anticipatory amounts and may not compound inordinate amounts or copies of commercially available drugs. *See* FFDCA § 503A; 21 U.S.C. § 353a.

251. DermaTran violates both of these requirements. It does not compound drugs pursuant to prescriptions, but rather creates its own formulas and goes out to market them to physicians. DermaTran's use of preprinted prescriptions pads and set numbered formulas makes clear that it is pushing its products on physicians and patients, not compounding ingredients in response to their individualized request.

252. DermaTran compounds large quantities of drugs at a time, sometimes as much as 10,000 to 15,000 grams at once, and often prepares several batches of the same formula on successive days. These products are not compounded in response to individual prescriptions.

253. DermaTran's use of Lidocaine formulas makes clear that its compounds are essentially copies of commercially available drugs or in some cases very expensive direct substitutes.

254. Finally, DermaTran, despite its claims, is not a retail pharmacy. At its height DermaTran processed thousands of prescriptions monthly, but nearly all of its business is done by mail order. It sees no more than five to ten patients monthly in its "retail" location.

255. DermaTran is, under the law, a manufacturing facility, which produces new drugs not approved for sale by the FDA and not produced subject to Good Manufacturing Procedures.

256. Its drugs are, therefore, misbranded under FDA regulations. Misbranded drugs are ineligible for reimbursement by any Government Health Care Program and each such claim is false and/or fraudulent under the FCA.

F. Damages

1. Damages from Kickbacks and Bribes

257. Relator estimates that DermaTran's total revenues amount to more than $100 million from inception in 2012 to 2017, of which Relator estimates at least 40% is Government Health Care Program business. Relator estimates that TRICARE business has been around $10 million in total. The majority, if not all, of this business is tainted by violations of the Anti-Kickback Statute, the Stark Statute, and TRICARE's fraud and abuse regulations due to DermaTran's pervasive policy and practice of paying cash bribes to physicians to prescribe its products, of illegally and routinely waiving patient copayments and deductibles, and of paying illegal sales commissions to sales staff. These policies and practice all served to induce the Government Health Care Program segment of DermaTran's business, which DermaTran would not otherwise have won. Therefore, Government damages amount to all or almost all of DermaTran's Government Health Care Program business.

258. The Government's damages include the Government portion of Pharmacy Defendants' business that was referred from DermaTran after insurers cancelled contracts with DermaTran because of DermaTran's fraudulent schemes.

259. The Government's damages include the Government portion of the Marketing Client Defendants' business that was tainted by DermaTran's illegal marketing agreements.

2. Damages from Price Manipulation

260. DermaTran's routine price manipulations, as illustrated by its failure to report accurately the usual and customary price of its medications, further tainted an unknown portion of DermaTran's Government Health Care Program revenues arising from the difference between the inflated prices charged to Government Health Care Programs and cash prices charged to the general public. Furthermore, DermaTran's illegal NDC testing procedure resulting in medically unnecessary formulations of compounded drugs taints an unknown portion of its Government Health Care Program revenues (including its $10 million TRICARE business), providing an additional basis for deeming DermaTran's Government business to be Government damages.

3. Damages from Lies and Misrepresentations

261. DermaTran's improper and illegal marketing of its compounded medications and use of false and misleading statements to promote its products are pervasive and taint an unknown portion, likely the majority, of its Government Health Care Program business, resulting in Government damages.

4. Damages from Conspiracy

262. Defendants are jointly and severally liable for all damages resulting from their illegal schemes and conspiracy.

G. Retaliation Against Relator

263. Relator was formally employed by State Mutual but assigned to work at DermaTran. Relator's employment terms and status were determined by, *inter alia*, Yancey and Moss (State Mutual, DermaTran, Yancey, and Moss, hereinafter "the Retaliation Defendants").

264. In 2017, as a result of deteriorating business prospects at DermaTran, Relator was due to be laid off. Relator was informed that this was not the result of deficient job performance, but strictly due to the lack of revenue.

265. Relator was offered a "Severance Agreement and General Release" which, in exchange for broad waivers of potential claims, provided Relator with, *inter alia*, the equivalent of four months' pay.

266. Subsequently, State Mutual requested that Relator continue to work and assist DermaTran's response to the Government's investigation in this matter. As a result, the Settlement Agreement and General Release was rendered moot.

267. Relator continued to work through the end of December 2017. On or about January 12, 2018, Relator was presented with another "Severance

Agreement and General Release" substantially similar to the prior document and again offering the equivalent of four months' pay.

268. State Mutual representatives described this offer as the standard or usual offer made to State Mutual employees in Relator's position.

269. Relator engaged independent counsel to assist with negotiation and execution of the severance agreement. Relator's counsel negotiated in earnest with representatives of State Mutual and DermaTran.

270. On or about February 15, 2018, the Retaliation Defendants abruptly ceased negotiating with Relator's attorney and for the first time accused her of obtaining and keeping State Mutual and DermaTran "property," threatening to utilize the "criminal courts" to seek "full restitution" from Relator.

271. Subsequent communications revealed that the Retaliation Defendants had performed forensic examinations of Relator's work computer and had concluded that Relator had moved and or copied unspecified files. Retaliation Defendants demanded that Relator and Relator's lawyer "assist" them with an "internal investigation" of Relator's own conduct.

272. Retaliation Defendants professed concern about potential HIPAA liability and compliance with the Government's investigation, but such concerns were, in fact a pretext for Retaliation Defendants' true concern - that Relator had

engaged in protected whistleblower activities to alert government authorities to Defendants long running fraudulent activities and to assist in the government in its investigation.

273. Retaliation Defendants also demanded that Relator sign an affidavit on the pains and penalties of perjury stating, in part, that at no point during Relator's employment did Relator delete, download, share, forward, or provide to anyone or any entity "files, records or data of any type containing emails, word processing files, calendars, voice messages or any prescriptions, accounting records, business forms, patient files, payor files, personnel files, or any other DermaTran business record of any type."

274. These requests were far broader than Retaliation Defendants' professed concerns, and apart from sweeping in plainly neutral activity such as forwarding emails, confirmed that Retaliation Defendants' true concern was that Relator had engaged in protected whistleblower activity. In Relator's experience, no other employee had ever been asked to sign an equivalent affidavit as part of a severance agreement. Relator refused to sign such an affidavit.

275. Retaliation Defendants thereafter refused to negotiate Relator's severance and rescinded their prior offers of severance pay.

VI. CLAIMS FOR RELIEF

Count I

Federal False Claims Act – False Claims
31 U.S.C. § 3729(a)(1)(A) (2009)

276. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

277. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*., as amended.

278. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval.

279. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.

280. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

281. Additionally, the United States is entitled to the maximum penalty of up to $22,363 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count II

Federal False Claims Act – False Records or Statements
31 U.S.C. § 3729(a)(1)(B) (2009)

282. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

283. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

284. By and through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

285. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

286. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

287. Additionally, the United States is entitled to the maximum penalty of up to $22,363 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count III

Federal False Claims Act – Reverse False Claims 31 U.S.C. § 3729(a)(1)(G) (2009)

288. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

289. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*., as amended.

290. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the Government and they have concealed and improperly avoided an obligation to pay money to the Government, including specifically Defendants' obligation to report and repay past overpayments of Medicare and other government health care program claims for which Defendants knew they were not entitled to and therefore refunds were properly due and owing to the United States.

291. The Government, unaware of the concealment by the Defendants, has not made demand for or collected the years of overpayments due from the Defendants.

292. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

293. Additionally, the United States is entitled to the maximum penalty of up to $22,363 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count IV

Federal False Claims Act - Conspiracy
31 U.S.C. § 3729(a)(1)(C) (2009)

294. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs above as though fully set forth herein.

295. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*., as amended.

296. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that tens of millions of dollars in payments from the federal government have been received in violation of the False Claims Act, and in violation of the Anti-Kickback Statute's, the Stark Statute's, and the TRICARE fraud and abuse regulations' prohibitions on receipt of payment for services rendered in connection with an improper financial arrangement, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.

297. The Government, unaware of the Defendants' conspiracy and fraudulent schemes, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

298. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

299. Additionally, the United States is entitled to the maximum penalty of up to $22,363 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count V

Retaliation in Violation of False Claims Act 31 U.S.C. § 3730(h)

300. Relator realleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

301. Retaliation Defendants harassed, discriminated against, wrongfully terminated, threatened, and rescinded an offer of severance pay because of lawful acts Relator undertook to stop violations of, and a conspiracy to violate, the False Claims Act. Defendants' retaliation also independently violates the FCA, 31 U.S.C. § 3730(h).

302. Retaliation Defendants' retaliation and discrimination has inflicted damages on Relator including, but not limited to, past and future earnings, lost

employment benefits (including health insurance benefits and retirement contributions), job-search expenses, humiliation, mental anguish, and emotional distress, all collectively in an amount to be determined at trial.

303. Retaliation Defendants' actions were knowing, malicious, willful, and with conscious disregard for Relator's rights under the law. Relator is further entitled to exemplary and punitive damages in an amount to be determined at trial.

VII. PRAYERS FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants are enjoined from violating the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*;

B. That judgment be entered against Defendants and in favor of the United States and the Relator in an amount equal to three times the amount of damages caused by Defendants' misconduct, as well as a civil penalty for each FCA violation in the maximum statutory amount;

D. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by its wrongful conduct and be enjoined from further distribution of compounded products distributed in violation of law;

E. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, litigation costs, expert fees, and all attorneys' fees permitted under 31 U.S.C. § 3730(d);

F. That Relator be awarded the maximum amount permitted under 31 U.S.C. § 3730(d);

G. That Relator be awarded all available damages, prejudgment interest, fees and costs pursuant to Relator's personal claims for retaliation under the federal FCA, 31 U.S.C. § 3730(h), including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement or in lieu thereof front pay, and compensation for any special damages and/or exemplary or punitive damages, and litigation costs, and attorneys' fees; and

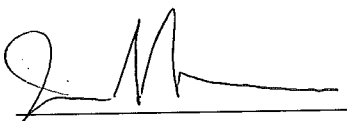
H. That the Court award such other relief as the Court deems proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff-Relator requests a jury trial.

June 5, 2018

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I have this day, June 5, 2018, served a true and accurate copy of the foregoing by Priority mail, with adequate postage affixed thereto, addressed to:

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Assistant U.S. Attorney
United States Attorney's Office
Richard B. Russell Building
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Atlanta, GA 30303

Sheri Lang