

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION

UNITED STATES OF AMERICA, <i>ex rel.</i> , DWAYNE THORNTON	)	No. 8: 15-CV-2647-T-36JSS
	)	
Plaintiff-Relator,	)	<b>SECOND AMENDED</b>
	)	<b>COMPLAINT</b>
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA,	)	<b>AND DEMAND FOR</b>
	)	<b>JURY TRIAL</b>
<i>c/o</i>	)	
	)	
UNITED STATES ATTORNEY FOR THE MIDDLE DISTRICT OF FLORIDA	)	
	)	
and	)	
	)	
ATTORNEY GENERAL OF THE UNITED STATES	)	
	)	
v.	)	
	)	
NATIONAL COMPOUNDING COMPANY, INC.,	)	
	)	
FORT MYERS BEACH PHARMACY HOLDINGS, LLC,	)	
	)	
FORT MYERS BEACH PHARMACY, LLC,	)	
	)	
SOOTHE ENTERPRISES, LLC,	)	
	)	
SOOTHE PERSONALIZED NUTRITION, LLC,	)	
	)	
SOOTHE PHARMACY, INC.,	)	
	)	
SOOTHE COMPOUNDING PHARMACY,	)	
	)	
SOOTHE PERSONALIZED RX,	)	
	)	
SOOTHE NUTRITION AND SUPPLEMENTS,	)	
	)	

SOOTHE PHARMACY, )  
)  
SOOTHE PERSONALIZED HEALTH & )  
NUTRITION, )  
)  
FRANK DESTEFANO, )  
)  
BRAD LONG, )  
)  
C.V. MCDOWELL MEDICAL, INC., )  
)  
C.V. MCDOWELL, LLC )  
(also d/b/a C.V. McDowell Medical, Inc.) )  
)  
MCDOWELL COMPANIES, INC. )  
)  
JACK L. STAPLETON, )  
)  
JACK H. STAPLETON )  
)  
GREAT WHITE SHARK OPPORTUNITY )  
FUND, L.P., )  
)  
GREAT WHITE SHARK OPPORTUNITY )  
FUND MANAGEMENT, LLC, )  
)  
ROBUSTO ENTERPRISES, LLC, )  
)  
EDUARDO “EDDIE” LOPEZ, )  
)  
Defendants. )  
\_\_\_\_\_ )

1. This is an action filed under the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, by Plaintiff-Relator Dwayne Thornton in the name of the United States, and himself to recover penalties and damages arising from alleged False Claims Act violations resulting from illegal activities related to the provision of compound pharmaceutical products.

2. The Defendants knowingly submitted or caused to be submitted false claims to Medicare, Tricare and other government programs to pay for compound pharmaceutical products. The prescriptions for these products were generated through kickbacks and illegal marketing practices and often were not even wanted by the patients, much less medically necessary.

### **JURISDICTION AND VENUE**

3. This action arises under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729, *et seq.*
4. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331 and the False Claims Act confers nationwide jurisdiction and venue.
5. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because the Defendants regularly transact business in this District, and did so at all times relevant to this Complaint and in addition to the fact that the Plaintiff-Relator resides in this District, at least one Defendant maintains offices or resides in this jurisdiction.

### **PARTIES**

#### **A. Plaintiff-Relator**

6. Plaintiff-Relator Dwayne Thornton served both as Vice President of Pharmacy Operations and as Director of Operations/Pharmacy Services for Defendant “Soothe Pharmacy, Inc.” and “Soothe” related entities as described in paragraphs 13-22 below from June of 2014 until April of 2015. For the majority of his tenure Mr. Thornton reported to Defendant, Brad Long.

7. Mr. Thornton holds an MBA from the University of North Carolina and a Bachelor of Science in Pharmacy from the University of Florida.
8. There has been no public disclosure of the allegations contained herein.
9. Plaintiff-Relator Dwayne Thornton is an original source of the allegations contained herein within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(B).
10. Mr. Thornton has direct and independent knowledge of the allegations in this disclosure and he has provided substantially all material evidence and information regarding these allegations to the government of the United States prior to filing this action.
11. In fulfillment of his obligations under 31 U.S.C. §§ 3730(b)(2) and 3730(e)(4)(B) the Plaintiff-Relator served the original Complaint on the United States immediately after it was filed under seal.

**B. Defendants**

**1. Pharmacies**

12. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
13. Defendant National Compounding Company, Inc. of 1003 8<sup>th</sup> Avenue W. Bradenton, FL 34205 and at several additional addresses in Florida is listed as the owner of the “fictitious name” of Soothe Compounding Pharmacy of 5009 Ashley Parkway Sarasota FL 34241 and Soothe Personalized Rx of 11047 Gatewood Drive Bradenton, FL 34211. Brad Long and Frank DeStefano are listed as officers of the company in filings with the State of Florida.
14. Defendant Soothe Enterprises, LLC of 1003 8<sup>th</sup> Avenue W. Bradenton, FL 34205 also lists Brad Long and Frank DeStefano as officers in filings with the State of Florida.

15. Defendant, Soothe Personalized Nutrition, LLC of 1003 8<sup>th</sup> Ave West, Bradenton, FL 34205 owns the “fictitious name” of Soothe Nutrition and Supplements as listed in filings with the State of Florida and lists Brad Long and Frank DeStefano as officers.
16. Defendant, Fort Myers Beach Pharmacy, LLC of 1003 8th Avenue West Bradenton FL 34205 owns the “fictitious names” of Soothe Personalized Health & Nutrition and Soothe Pharmacy both of 1003 8<sup>th</sup> Avenue W. Bradenton, FL 34205.
17. Defendant, Fort Myers Beach Pharmacy Holdings, LLC of 17274 San Carlos Blvd Suite 205, Fort Myers Beach Florida 33931 is listed as manager of Defendant Fort Myers Beach Pharmacy, LLC also of 17274 San Carlos Blvd Suite 205, Fort Myers Beach Florida 33931 in filings with the state of Florida signed by Frank DeStefano.
18. The Defendants National Compounding Company, Inc., Fort Myers Beach Pharmacy, LLC, Fort Myers Beach Pharmacy Holdings, LLC, Soothe Enterprises, LLC and Soothe Personalized Nutrition, LLC are engaged in the compound pharmacy business and own or control several entities and “fictitious names” as listed with the Florida Department of State Division of Corporations, including, but not limited to:
  - i. Soothe Pharmacy,
  - ii. Soothe Compounding Pharmacy,
  - iii. Soothe Personalized Rx,
  - iv. Soothe Nutrition and Supplements,
  - v. Soothe Personalized Nutrition, LLC,
  - vi. Soothe Personalized Health & Nutrition
  - vii. Soothe Enterprises, LLC

19. The “fictitious names” businesses and entities listed above in paragraph 18, at i-vii are all hereby listed as Defendants in this action.
20. Defendants listed in paragraphs 13-19 also do business under the name “Soothe Pharmacy, Inc.” which appears on their website and is also hereby listed as a Defendant in this action.
21. Defendant, Frank DeStefano of 1003 8<sup>th</sup> Avenue West Bradenton, FL 34205 is one of the principal owners of Soothe including, the National Compounding Company and Fort Myers Beach Pharmacy Holdings, LLC, Fort Myers Beach Pharmacy, LLC, Soothe Enterprises, LLC, and Soothe Personalized Nutrition, LLC.
22. Defendant Brad Long, of 1003 8<sup>th</sup> Avenue West Bradenton, FL 34205 is one of the principal owners of Soothe including the National Compounding Company and Fort Myers Beach Pharmacy Holdings, LLC, the Fort Myers Beach Pharmacy, LLC Soothe Enterprises, LLC and Soothe Personalized Nutrition, LLC.
23. All Defendants listed in paragraphs 13-22 are hereinafter sometimes collectively referred to as “Soothe” or the “Soothe Defendants.” Whenever knowing conduct is alleged against the “Soothe Defendants” said allegations include knowing conduct by individual Defendants DeStefano and Long as well as all of the entities named as part of the Soothe Defendants.
24. Other pharmacy entities involved in the alleged schemes but, not named as defendants in this Second Amended Complaint include Campbell’s Pharmacy, Century Pharmacy, LLC (hereinafter “Century Pharmacy”), Professional Compounding Pharmacy,

InforMD Solutions, West Chase Compounding Pharmacy (hereinafter “West Chase Pharmacy”), Wiley's Pharmacy & Compounding Service, Inc, and Affordable Medical Solutions.

## **2. Representative Groups**

25. Defendant C.V. McDowell Medical, Inc. of 2740 E. Oakland Park Boulevard., Suite 205, Fort Lauderdale, Florida 33306, c/o Jack L. Stapleton, Registered Agent, generated prescriptions for compound pharmaceutical products which it then sells on a commission basis to pharmacies to fill the order.
26. Defendant C.V. McDowell, LLC of 2740 E. Oakland Park Blvd., Suite 205, Fort Lauderdale, Florida 33306, generates prescriptions for compound pharmaceutical products, which it then sells on a commission basis to pharmacies to fill the order. C.V. McDowell, LLC also did business as and operated under the “fictitious name” of C.V. McDowell Medical, Inc. and registered “C.V. McDowell Medical, Inc.” as a “fictitious name” through C.V. McDowell, LLC.
27. Defendant McDowell Companies, Inc. of 2740 E. Oakland Park Blvd., Suite 205, Fort Lauderdale, Florida 33306, generates prescriptions for compound pharmaceutical products which it then sells on a commission basis to pharmacies to fill the order.
28. Defendant Jack L. Stapleton of 2740 E. Oakland Park Blvd., Suite 205, Fort Lauderdale, Florida 33306, owns and is the managing member of C.V. McDowell Medical, Inc., is the managing member of C.V. McDowell, LLC and the entity that operated under the “fictitious name” of C.V. McDowell Medical, Inc., and he is the registered agent and officer/director of McDowell Companies, Inc.

29. Defendant Jack H. Stapleton of 2740 E. Oakland Park Blvd., Suite 205, Fort Lauderdale, Florida 33306, is an authorized member of C.V. McDowell, LLC.
30. The Defendants named in paragraphs 25-29 are hereinafter sometimes collectively referred to as “C.V. McDowell” or the “C.V. McDowell Defendants.” Whenever knowing conduct is alleged against the “C.V. McDowell Defendants” said allegations include knowing conduct by individual Defendants Jack L. Stapleton and Jack H. Stapleton as well as all of the entities named as part of the C.V. McDowell Defendants.
31. Defendant Robusto Enterprises, LLC of 50 Central Ave Sarasota Florida 34236, c/o David Saslow, registered agent, generates prescriptions for compound pharmaceutical products which it then sells on a commission basis to pharmacies to fill the order. Robusto Enterprises, LLC shares common management with Defendants Great White Shark Opportunity Fund, L.P. and Great White Shark Opportunity Fund Management, LLC as David Chessler is a manager of all three entities.
32. Defendant Great White Shark Opportunity Fund Management, LLC, of 50 Central Avenue Suite 950, Sarasota Florida 34236, c/o David Chessler, manager and registered agent, shares common management and worked in conjunction with Defendants Robusto Enterprises, LLC and Eduardo Lopez, and Great White Shark Opportunity Fund, L.P., to generate prescriptions for compound pharmaceutical products which were sold on a commission basis to pharmacies to fill the order.
33. Defendant Great White Shark Opportunity Fund, L.P., a Delaware limited partnership, c/o Corporate Creations Network, Inc., registered agent, at 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, DE 19810, shares common management and



worked in conjunction with Defendants Robusto Enterprises, LLC and Eduardo Lopez, and Great White Shark Opportunity Fund, L.P., to generate prescriptions for compound pharmaceutical products which were sold on a commission basis to pharmacies to fill the order.

34. Defendant Eduardo “Eddie” Lopez of 50 Central Avenue Suite 950, Sarasota Florida 34236 manages Robusto Enterprises, LLC and Defendant Lopez expressly held himself out as a representative of the “Great White Shark Opportunity Fund” when communicating with the Soothe Defendants and working to generate prescriptions for compound pharmaceutical products which were sold on a commission basis to pharmacies to fill the order.
35. The Defendants named in paragraphs 31-34 are hereinafter sometimes collectively referred to as the “Robusto Enterprises Defendants.” Whenever knowing conduct is alleged against the “Robusto Enterprises Defendants” said allegations include knowing conduct by individual Defendant Eddie Lopez as well as all of the entities named as part of the Robusto Enterprises Defendants.
36. Other representative group entities involved in the alleged schemes but not named as defendants in this Second Amended Complaint include Top Tier Medical, LLC (hereinafter “Top Tier”), Unique Media Solutions, Marvel Marketing Group, LLC (hereinafter “Marvel Marketing”), Tomahawk Medical, LLC (hereinafter “Tomahawk Medical”), and Products for Doctors, Inc. (hereinafter “Products for Doctors”).

## FACTUAL ALLEGATIONS

### A. Introduction

37. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
38. Compound pharmaceuticals are purchased by prescription with funds from Medicare, Medicaid and Tricare among other government programs.
39. Soothe conducted business on a regular basis with all the representative groups listed above and also worked with competitor pharmacies listed above.
40. As a result of working for Soothe and attempting to improve its practices, the Plaintiff-Relator obtained direct knowledge of all the information contained herein, in addition to learning about Soothe's own actions to defraud government programs.
41. Compound pharmaceuticals are extremely profitable products. Government health care programs pay for these products at high rates, because, at least in theory, the compounds must be created on a per order basis.
42. Indeed the Food and Drug Administration states a licensed pharmacist or physician may compound a drug if he or she:
- Does not compound regularly or in inordinate amounts (as defined by the secretary) any drug products that are essentially copies of a commercially available drug.
- 21 C.F.R. §353a(b)(1)(D).
43. Obtaining a single prescription for a compound pharmaceutical product can be worth thousands of dollars. If such prescriptions are re-filled a single patient can be a source of a large amount of revenue for these companies.

44. The Food and Drug Administration also requires these prescriptions to be obtained without advertising and promotion of any specific compound.

A drug may be compounded under subsection (a) of this section only if the pharmacy licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist or, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

21 C.F.R. §353a(c).

45. The representative groups work on commission. They obtain a percentage of any such order. Indeed, at least one such group, the Robusto Enterprises Defendants, took as high as 70% of the value of the prescription when Defendant Eddie Lopez, acting on the Robusto Enterprises Defendants' behalf, brought business to a pharmacy.
46. To the extent that the representative groups are employed by anyone other than themselves it would be the pharmacies. The arrangements are made to increase business and sales only, not to provide health care services to patients.
47. The representatives obtain prescriptions through several marketing efforts. Often the representatives call lists of people known to suffer from painful conditions.
48. For example, the representatives will call patients with diabetes, cardiovascular and other diseases to get their consent to obtain a prescription from a doctor for various medications. Representatives also obtain prescriptions through calls to doctors and through physicians with whom they have an ongoing relationship.
49. The products involved are usually creams related to treatment for pain, wounds, scar and similar conditions. Specific compounds are sold in this manner and in large quantities.

50. The patients may tell the representatives that they do not need these creams, as they may not have a scar or have pain. They may, of course, indicate that they want the product. In any event a major selling point to the patients is that the medication is generally offered free of charge.
51. This creates problems, when the patient receives a bill for a co-payment.
52. Indeed, the Plaintiff-Relator wrote an email on Friday October 31, 2014 to Soothe's executives (including Defendants Brad Long and Frank Destefano) listing 11 patients raising complaints for that week, generated as a result of an initial attempt to collect a co-payment by Soothe. The patients complained that employees working for the C.V. McDowell Defendants had assured 10 of them there would be no charge or the prescription was free. One patient said their doctor did not want the patient taking the crème and did not write the prescription.
53. The representative groups, including the C.V. McDowell Defendants and the Robusto Enterprises Defendants, and non-parties Sean Beck through Marvel Marketing, Will Kimball through Unique Media Solutions, and Products for Doctors, all engaged in the marketing practices, kickback schemes and fraudulent conduct alleged herein.
54. The representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) engaged in these practices to the degree that the compound pharmacies (including the Soothe Defendants) were aware of this activity. The Soothe Defendants had to be aware of it because any attempts to collect co-payments were met with discontent and threats to take prescriptions to another pharmacy.

55. The very fact that the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) provided business to the pharmacies through a commission structure basis creates a series of violations of the Anti-Kickback Statute (“AKS”) for illegal remunerations. The representative groups are soliciting payment in exchange for purchasing or arranging for purchasing of products purchased under government health care programs and of course the pharmacies are making the payment in exchange. This activity does not fall within any safe harbor provision of the AKS. See, 42 U.S. Code § 1320a–7b(b)(1)(b) and (2)(b).
56. Pharmacies (including the Soothe Defendants) could also see when prescriptions are forwarded electronically with a fax banner showing that the prescription went from representative group to the pharmacy and not directly from the doctor’s office.
57. Representative groups (including, but not limited to, the C.V. McDowell Defendants and the Robusto Enterprises Defendants) have the prescription faxed back to themselves for distribution to pharmacies to control the prescription and ensure they can obtain a share of the value of the prescription.
58. Prescriptions are supposed to be provided from the doctor directly to the pharmacy filling the order.
59. The Drug Enforcement Agency’s Pharmacist’s Manual makes clear that the pharmacist is responsible for ensuring these prescriptions are valid:

The dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

U.S. Department of Justice Drug Enforcement Administration Office of Diversion

Control Pharmacists Manual 2010, page 66.

60. Forwarding a prescription interferes with the relationship between the patient, doctor and pharmacist and interferes with the ability of pharmacist to be sure that the prescription is in fact ordered in the normal course of professional conduct as required for a valid prescription.
61. The Code of Federal Regulations contemplates the prescription being transmitted by “the practitioner or the practitioner’s agent to the pharmacy.” 21 C.F.R. § 1306.21(a) and (c).
62. However, these prescriptions were faxed from the doctor to a representative group who obtained the commission from the Pharmacy and therefore can hardly be considered to be the “agent” of the doctors.
63. The Soothe Defendants like their competitors accepted such prescriptions, which were generated from the representative groups listed above. The representative groups cited herein do business with many compound pharmacies on a nationwide basis if and when they can.
64. The actions taken by the pharmacies and the representative groups knowingly to fill prescriptions en masse and in fact generate the prescriptions in the first place, often without medical necessity or documentation of medical necessity violates the pharmacy responsibility to handle only valid prescriptions.
65. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the

meaning and intent of the Controlled Substances Act, See 21 U.S.C. Subchapter I, Part C § 829.

**B. Transferring prescriptions in exchange for fees.**

66. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
67. In order to obtain a payment for a prescription the compound pharmacy must fill the prescription. Sometimes for many different reasons the pharmacy may not be able to fill the order.
68. For example, Soothe had an arrangement to handle particular transfers through Century Pharmacy. It was an even 50/50 split when Soothe transferred a prescription to Century Pharmacy each company would earn 50% of the prescription value. This happened when Soothe obtained a prescription insured through Caremark, which handled Federal Employee Plan insurance processing. Soothe was not eligible to receive funds directly from Caremark so they worked through Century Pharmacy to fill these orders. In this way Soothe was able to get funds for a prescription it otherwise would not have been able to fill. By splitting the fees from the prescription Soothe gets money it otherwise is not entitled to obtain and Century Pharmacy is accepting a kickback to fill a prescription.
69. In such cases, the pharmacy is supposed to arrange a transfer of the prescription to a pharmacy which could fill the prescription without collecting a fee.
70. The Defendants however, transfer the prescriptions en masse from one pharmacy to the other usually in exchange for a fee or percentage of the prescription.

71. Many state laws also make this kind of fee splitting illegal. For example, Title XXXII of the 2012 Florida Statutes as follows:

**459.015 Grounds for disciplinary action; action by the board and department.**

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):  
capacity as a licensed osteopathic physician.

...

(j) Paying or receiving any commission, bonus, kickback, or rebate, or **engaging in any split-fee arrangement** in any form whatsoever with a physician, organization, agency, person, partnership, firm, corporation, or other business entity, for patients referred to providers of health care goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers, or pharmacies. The provisions of this paragraph shall not be construed to prevent an osteopathic physician from receiving a fee for professional consultation services.

[Emphasis supplied.]

72. The only reason a transfer occurs between the pharmacies regarding multiple prescriptions is for one pharmacy to receive a share of the bill to the government program. This is fee sharing and an inducement for one pharmacy to transfer the prescriptions to the other.
73. As such these arrangements also violate the Anti-kickback Statute 42 U.S.C. § 1320a-7b(b)(1) and (2) both for receiving such remuneration and for offering such remuneration.
74. The referral of the patient from one pharmacy to the other creates illegal remuneration in exchange for the referral. Such arrangements also therefore create liability under the False Claims Act under 42 U.S.C. §1320a-7b(g).



**C. Defendants knowingly did not collect co-payments to create kickback incentives.**

75. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
76. When Soothe began to attempt to collect co-payments from patients, that upset the business model established by the representative group's efforts (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) to generate prescriptions and pharmacies willingness to fill such prescriptions.
77. Indeed, Soothe lost prescriptions to other pharmacies including many of those listed above from when they told the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) that Soothe was going to attempt to collect co-payments in the last quarter of 2014 and first quarter of 2015.
78. One tactic used by the representative companies (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) is to tell the prospective patient that the prescription is or will be free.
79. While government programs do subsidize these products all of the Defendants knew or should have known that a co-payment is required under virtually any program to fill such a prescription. As a cost of doing business not collecting such a co-payment is a minor expense to any of the Defendants. As a result, the representative groups such as C.V. McDowell and Rubusto Enterprises would tell patients the compound prescriptions would either be free or provided at minimal cost, without mentioning that patients would be charged a co-pay, and the pharmacies such as Soothe generally would not bother to collect the co-payment or they would not make a serious attempt to collect

it. The pharmacies, including Soothe, would continue to send refills of prescriptions to patients even if patients did not make any co-payments.

80. However, each of the Defendants knew or should have known that not collecting the co-payment is an improper inducement to the patient to purchase the product. As a result, not collecting the co-pay is also a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1) and (2). Defendants' knowing failure to collect a co-payment therefore is automatically an act subject to liability under the False Claims Act.
81. Once Soothe decided, at the Plaintiff-Relator's urging, to attempt to collect the co-payments it lost clients to other pharmacies. Soothe eventually stopped working with representative groups after learning that many of the representatives (including those employed by the C.V. McDowell Defendants and the Robusto Enterprises Defendants) would not stop telling potential clients that the prescription was free.
82. When Soothe attempted to contact patients and collect co-payment or hold the prescription until they got the co-payment at least one other representative group (Unique Media and Will Kimball) asked Soothe to transfer prescriptions to another pharmacy and no longer did business with Soothe so far as Plaintiff-Relator is aware.
83. Attempts to avoid collecting co-payments also grew ever more sophisticated.
84. Unique Media's Will Kimball wanted "his" Tricare prescriptions sent to Professional Compounding Pharmacy because he claimed that pharmacy had a charity that donates money to cover co-payments owed by veterans. The Plaintiff-Relator could not confirm if the charity was in any way separate from Unique Media or Professional Compounding Company. In any event, Mr. Kimball became upset with Soothe when

- the Relator began attempts to collect co-payments and Mr. Kimball directed Tricare prescriptions he generated be sent to Professional Compounding Company Pharmacy.
85. Prescriptions generated by Will Kimball's company were almost all paid for by Tricare claims. He generally sent prescriptions to Professional Compounding Pharmacy, because that pharmacy did not collect co-payments.
86. Soothe and its owners were in negotiations to acquire West Chase Compounding Pharmaceuticals during the Plaintiff-Relator's tenure with Soothe. As a result, he learned about West Chase's solution to the problem of collecting co-payments.
87. West Chase created a marketing company and paid money to the company it created to provide co-payment assistance. The marketing company provided pre-paid debit cards, which could be used to pay West Chase Pharmacy for the co-payments of compound drugs ordered through West Chase Pharmacy. When the patient purchased the product it appeared that the co-payment was funded from sources other than the pharmacy itself, but in fact West Chase provided the funds.
88. The Plaintiff-Relator's latest information is that Soothe and West Chase have gone through with plans to join forces and that Soothe obtained venture capital funding for this purpose.
89. Affordable Medical Solutions provided a special service to pharmacies in need of showing that they collected co-payments. The company would in effect "insure" co-payments. If a pharmacy wanted to fill a prescription Affordable Medical Solutions would claim it had been paid on the company's behalf. When, as, and if, an audit occurred Affordable Medical Solutions would pay the co-payment and provide

documentation that it had done so. When there was no audit no such assurance or payment would be made.

90. Ultimately Soothe's association with Affordable Medical Solutions cost Soothe deeply. Caremark, the company charged with handling Federal Employee plan claims questioned Soothe's prescriptions, which indicated that a "trust" was paying for the balance of co-payments. Soothe had collected for example \$30 on a co-payment requirement of \$300. Caremark found no such trust existed.
91. When pressed on the issue Jay Wiley the owner of Affordable Medical Solutions denied having told Soothe officials about such a trust despite the fact that the Plaintiff-Relator's predecessor Sean Hogan had continually marked co-payment prescriptions as having been paid for through such a trust. Affordable Medical Solutions owner also owns a pharmacy, and Mr. Wiley's scheme to provide "co-payment insurance" was adopted in the compound pharmacy industry.
92. Virtually all the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) and the pharmacies listed knew that co-payments for compound pharmaceuticals were not being collected and, in fact, the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) and the Defendants' knowing failure to collect co-payments was part of the fraudulent scheme alleged herein.

**D. Automatic refills filled.**

93. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.

94. Many of the actions taken by the pharmacies and the representative groups are so egregious as to run afoul of the general requirements for a valid prescriptions presented in the Drug Enforcement Administration's Pharmacist's Manual Section IX:

A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

95. The Representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) not only obtain prescriptions, which they fax to the pharmacy as opposed to having a physician do so, and which the pharmacies then fill, they also do not obtain separate documentation that a re-fill has been requested or authorized.
96. The Robusto Enterprises Defendants just used a form with a box anyone could check. It was impossible, based on a review of the form, for the pharmacy to be sure that the box was checked by an appropriate provider.

97. InforMD would fill the prescriptions on the basis of the check mark on the bottom of the script. They obtained automatic refills every month of earlier prescriptions in this manner.
98. Soothe's use of pre-printed forms had come to the attention of the State of Rhode Island which reprimanded Soothe for the practice in violation of RIGL § 5-19.1-21 and § 27 of the rules and regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributers.
99. Specifically, the State of Rhode Island found that Soothe faxed a "pre printed prescription form to a Rhode Island physicians office, which did not have the name of the physician on the prescription order and did not have the date of issuance on the prescription order. This was taken by the State of Rhode Island to be a violation of RS-19.1-PHAR and RIGL § 5-19.1-5 as the "the licensee made and/or filed false reports or records."
100. The Plaintiff-Relator, while working for Soothe, attempted to obtain more documentation to substantiate such refills. He instituted a policy that required a separate letter for a re-fill.
101. Many states allow for the use of pre-printed prescription forms, many do not and many such as Florida appear not to address the issue.
102. As the Rhode Island incident indicates even states such as Rhode Island that do not strictly make using pre-printed forms illegal nonetheless expect prescriptions, even for re-fills to otherwise comport with their regulations.

103. The pharmacies (including Soothe) and representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) not only used pre-printed forms they did not bother to determine that the patients actually needed the medicine and did not require additional documentation to be sure the patients needed re-fills.

104. The pharmacies not only are required to determine that the prescription is issued in the normal course of treatment but also are required to maintain a compliance program to be sure these activities comport with regulations and do not lead to fraud waste and abuse.

See for example, the CMS Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines, which requires a compliance program be instituted in order to protect against fraud. To the extent the Defendant-pharmacies have such programs they failed at detecting such fraud.

105. Representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants and Top Tier) were all engaged in these practices. They worked with Soothe and undoubtedly many other pharmacies to fill and re-fill prescriptions quickly in order to maximize revenue as part of the fraudulent scheme to knowingly submit or cause to submit false claims to the United States.

106. The Defendants were able to accomplish this through the use of pre-printed prescription pads and faxes of forms from the representative groups to the pharmacies.

107. All the Defendant-representatives groups listed use and all the Defendant-pharmacies accept prescriptions printed on pre-printed prescription pads.

108. In the Plaintiff-Relator's experience Soothe seldom received a prescription, which was not from a pre-printed pad.

109. All Defendants were engaged in the practices described in this section and all the representative groups knowingly presented such prescriptions to Soothe directly, knowing that false claims for reimbursement from Tricare or other government health care payors would be submitted.

**E. Defendants did not assure prescriptions were from doctors licensed in the same state as the patient, or that other particular state laws were followed.**

110. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.

111. The entire compound pharmacy practice is subject to this issue and the Defendants listed herein are particularly unable to follow the requirements.

112. It is admittedly difficult to keep track of the many state laws, which govern the practice of pharmaceutical distribution. On the other hand, the Defendants knowingly sell compound pharmaceuticals on a national basis through internet and telephone marketing. In so doing they accept the burden of comporting with all the state laws in which they sell these products.

113. When such prescriptions are issued contrary to law or absent a valid license to a patient in a distant state that creates an illegal prescription under state law. It was a well-known issue within the industry that, while these companies handled prescriptions nationwide, few were able to keep up with the licensing requirements of all the states. It is inevitable that many prescriptions were filled in violation of the state law from which they were ordered.



114. Defendants including but not limited to Soothe and C.V. McDowell fail to ensure that physicians were licensed appropriately in the state for the patient for the prescription to be legal. Indeed, the Plaintiff-Relator was aware of only one telemarketing company who is not a Defendant in this action, that did in fact pay attention to this responsibility.
115. There was otherwise no attempt to be sure that physicians were licensed in the appropriate state as the patient. Soothe at the direction of the Plaintiff-Relator did make some attempt to correct this issue, but all Defendants failed to follow the applicable requirements.

**F. Defendants manipulated the formulas in the compound product to drive up the cost of the product and the cost to the government.**

116. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
117. Plaintiff-Relator analyzed the billing by Soothe over a period of a year.
118. Flurbiprofen is a NSAID or non-steroidal anti-inflammatory drug.
119. Fluticasone is a corticosteroid.
120. Soothe used both of these ingredients to drive up the costs of compounds. Fluticasone was used at doses of up to 1%, which is 20 times the amount of the commercially manufactured dose of .05%.
121. Flurbiprofen was chosen as a NSAID solely because of high Average Wholesale Price (“AWP”) and reimbursement. Compared to many equally effective alternatives, such as Ketoprofen, it is more difficult to compound with other substances and often required additional steps to keep the creams from hardening. The reason it was used was to drive up the costs of the compounds sold by Soothe.

122. The maximum recommended oral dose of Flurbiprofen is 300mg per day. It is not sold commercially as a cream. The compounded creams often contained 100mg to 200mg per pump and were dosed 1-2 pumps 3-4 times daily. So, the daily topical dose of the creams was up to 1600 mg (more than 5 times the oral dose).
123. The Plaintiff-Relator reviewed approximately a year of orders at Soothe and found the Flurbiprofen and Fluticasone orders increased costs for no medical reason.
124. Formulas containing Flurbiprofen amounted to \$13,497,447 of business for Soothe. A full 29% of the revenue generated by these formulas was from Flurbiprofen, or \$3,914,259.
125. Meanwhile Ketoprofen is 72% less expensive than Flurbiprofen, easier to compound with, and just as effective. If Soothe had used Ketoprofen, it would have reduced the cost of these formulas by \$2,818,266.
126. Over the same period, Fluticasone formulas represented \$6,393,753. Some 66% (\$4,219,876) of the cost of these compounds was Fluticasone and Fluticasone was generally dosed at 1%, or twenty times the manufactured dose. If the dose of Fluticasone in these creams was lowered to the .05% as the manufacturer uses, it would have saved \$4,008,883.
127. These creams cost thousands of dollars per prescription and most, if not all, were billed to patients' insurance.
128. Indeed, over the period from late 2014 to mid 2015, most of the claims were paid by Tricare. This was true for the entire compounding industry as everyone involved learned Tricare was the easiest service to get claims paid.

129. When the Plaintiff-Relator raised this issue to management at Soothe he was told that if the doctor signs the prescription and it isn't hurting anyone, the government will not find out what happened.
130. The Plaintiff-Relator pushed particularly hard to get the Fluticasone doses lowered in formulas that were used for patients who had abraded skin because there could be more absorption of the drug in those cases. These discussions took place from the beginning of Mr. Thornton's employment at Soothe with Brad Long.
131. Mr. Brad Long, one of the owners of Soothe, tried to convince Mr. Thornton that 1% Fluticasone was safe and effective because it was not absorbed and works locally. Nonetheless, Mr. Long was unable to get any of the consultants he put on the phone with the Plaintiff-Relator to side with this assessment.
132. As a result, the Plaintiff-Relator attempted to have Soothe lower Fluticasone in some formulas. When he did so Soothe alienated Top Tier Marketing and its principal Wayne Wilkerson who wanted the very profitable drug in the compound. That in turn raised the concern of the Soothe owners including Mr. Long that Soothe would lose representative groups to other pharmacies who were filling 1% Fluticasone prescriptions. Mr. Long was able to get Soothe to continue to use Fluticasone in amounts that exceeded the manufacturers recommendations.
133. Soothe was guilty of this practice and the representative groups all were involved in deliberately driving up the cost by creating formulas that maximize revenue to drive of their commissions without any advance in efficacy.

134. These representative groups, of course, all worked with numerous other pharmacies besides Soothe and it is the Plaintiff-Relator's best information that they were able to get other pharmacies to handle prescriptions in this manner.
135. The following chart illustrates representative examples of the false claims submitted to the United States Government through the billing of prescriptions generated by representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) to Tricare. This chart shows for each representative example of false claims submitted or caused to be submitted by Defendants: (1) the representative group which generated the prescription ("Rep. Group"); (2) the date the prescription was dispensed and thus billed to Tricare ("Date Disp."); (3) the alias of the patient prescribed ("Pt."); (4) quantity of the drug prescribed ("Qty."); (5) the drug prescribed ("Drug"); (6) the total amount billed to Tricare ("Total (\$)"); (7) the cost for the prescription ("Cost (\$)"); and (8) percent of profit from the prescription ("Prof. (%)").
136. For formatting reasons, the names of the following representative groups have been abbreviated in the chart below: 1) C.V. McDowell as "CV MCD."; 2) Robusto Enterprises as "ROBUSTO"; 3) Marvel as "MARV."; and 4) Will Kimball as "WILL KIMB." Additionally, all drug names are abbreviated including: 1) Flurbiprofen as "FLUR"; and 2) Fluticasone as "FLUT":

<b><u>Rep. Group</u></b>	<b><u>Date Disp.</u></b>	<b><u>Pt.</u></b>	<b><u>Qty.</u></b>	<b><u>Drug</u></b>	<b><u>Total (\$)</u></b>	<b><u>Cost (\$)</u></b>	<b><u>Prof. (%)</u></b>
CV MCD.	7/1/14	A	360	FLUR/BACL/CLON/ GABA/BUPI 20/2/0.2/10/3% CRE	4,371.00	176.40	95.96

<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
CV MCD.	7/14/14	B	240	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,219.52	199.97	93.79
TOP TIER	7/21/14	C	240	FLUR/GABA/BACL /CYCL/BUPI 20/10/2/3/2 % CREA	3,572.39	213.89	94.01
CV MCD.	7/23/14	D	360	FLUR/BACL/CLON/ GABA/BUPI 20/2/0.2/10/3% CRE	5,569.88	264.60	95.25
TOP TIER	8/1/14	E	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,490.48	1,067.28	89.83
CV MCD.	8/4/14	F	260	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	4,799.06	299.95	93.75
ROBU-STO	8/8/14	G	60	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	2,812.23	256.30	90.89
ROBU-STO	8/13/14	H	360	FLUR/TRAM/CLON /CYCL/BUPI/KETA 20/5/0.2/3/3/	5,289.04	339.30	93.58
CV MCD.	8/14/14	I	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,564.07	512.59	90.79
ROBU-STO	8/15/14	J	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,133.90	222.74	92.89
CV MCD.	8/21/14	K	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,564.07	512.59	90.79
TOP TIER	8/25/14	L	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,488.83	1,067.28	89.82
CV MCD.	9/2/14	M	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,564.07	512.59	90.79

<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
ROBU-STO	9/3/14	N	60	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	2,812.23	256.30	90.89
CV MCD.	9/9/14	O	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,564.07	512.59	90.79
TOP TIER	9/15/14	P	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,487.51	1,067.28	89.82
CV MCD.	9/23/14	Q	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,563.91	512.59	90.79
TOP TIER	9/24/14	R	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,487.54	1,067.28	89.82
ROBU-STO	9/29/14	S	120	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	1,352.14	100.51	92.57
CV MCD.	10/1/14	T	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	4,798.40	299.95	93.75
CV MCD.	10/2/14	U	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,758.68	230.08	93.88
ROBU-STO	10/2/14	V	60	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	1,229.18	75.14	93.89
TOP TIER	10/3/14	W	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,487.54	1,067.28	89.82
ROBU-STO	10/15/14	X	240	FLUR/LOPE/ CLON/CYCL/BUPI/ DMSO/MENT 20/5/	3,117.29	209.16	93.29

<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
CV MCD.	10/21/14	Y	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	4,798.40	299.95	93.75
TOP TIER	10/27/14	Z	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,487.54	1,067.28	89.82
MARV.	10/29/14	AA	360	FLUR/BACL/CYCL/ GABA/LIDO 20/4/2/10/5% CREA	5,268.14	254.95	95.16
CV MCD.	11/3/14	BB	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	4,798.40	299.95	93.75
ROBU-STO	11/7/14	CC	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,110.81	201.02	93.54
TOP TIER	11/7/14	DD	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/4%	10,430.43	1,061.38	89.82
CV MCD.	11/11/14	EE	200	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	9,232.91	854.32	90.75
MARV.	11/12/14	FF	360	FLUR/BACL/CYCL/ GABA/LIDO 20/4/2/10/5% CREA	5,268.14	254.95	95.16
MARV.	11/13/14	GG	360	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	16,570.92	1,537.78	90.72
ROBU-STO	11/20/14	HH	120	FLUT/LEVO/ PRIL/GABA 1/2/0.5/3/15% GEL	5,563.91	512.59	90.79
CV MCD.	11/24/14	B	240	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,219.07	199.97	93.79
TOP TIER	11/24/14	II	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/5%	10,487.54	1,067.28	89.82

<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
TOMA-HAWK	11/25/14	JJ	480	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	21,027.35	2,050.37	90.25
CV MCD.	12/1/14	KK	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,758.02	230.08	93.88
MARV.	12/3/14	LL	360	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	16,570.92	1,537.78	90.72
ROBU-STO	12/4/14	MM	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,110.81	201.02	93.54
TOP TIER	12/4/14	NN	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/4%	10,430.43	1,061.38	89.82
WILL KIMB.	12/5/14	OO	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,110.81	201.02	93.54
TOMA-HAWK	12/8/14	PP	60	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	2,812.15	256.30	90.89
CV MCD.	12/11/14	QQ	360	FLUR/BACL/CLON/ GABA/BUPI 20/2/0.2/10/3% CRE	3,758.02	230.08	93.88
WILL KIMB.	12/12/14	RR	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,110.81	201.02	93.54
ROBU-STO	12/18/14	SS	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,563.91	512.59	90.79
CV MCD.	12/24/14	TT	240	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,219.07	199.97	93.79



<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
TOMA-HAWK	12/24/14	UU	360	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	16,570.92	1,537.78	90.72
TOP TIER	12/24/14	VV	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/4%	10,430.43	1,061.38	89.82
WILL KIMB.	12/30/14	WW	360	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	16,570.92	1,537.78	90.72
ROBU-STO	1/1/15	XX	60	FLUT/LEVO/ PRIL/GABA 1/2/0.5/3/15% GEL	2,812.15	125.34	95.54
CV MCD.	1/12/15	YY	120	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	5,563.91	250.68	95.49
MARV.	1/12/15	ZZ	360	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	16,570.92	752.04	95.46
TOMA-HAWK	1/15/15	AA A	300	FLUR/BACL/CYCL/ GABA/LIDO 20/2/2/6/2% CREAM	3,588.41	168.99	95.29
TOP TIER	1/19/15	BBB	240	FLUR/GABA/BACL /CYCL/BUPI 20/10/2/3/2 % CREA	3,571.51	213.89	94.01
CV MCD.	1/20/15	I	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	4,798.40	299.95	93.75
ROBU-STO	1/23/15	CCC	240	FLUR/LOPE/ CLON/CYCL/BUPI 20/5/0.2/3/3% CREA	3,110.81	201.02	93.54
WILL KIMB.	1/23/15	DD D	240	FLUT/LEVO/ PENT/PRIL/ GABA 1/2/0.5/3/15% GEL	11,067.42	501.36	95.47
TOP TIER	1/26/15	EEE	240	FLUR/GABA/BACL /CYCL/BUPI 20/10/2/3/2 % CREA	3,571.51	213.89	94.01

<u>Rep. Group</u>	<u>Date Disp.</u>	<u>Pt.</u>	<u>Qty.</u>	<u>Drug</u>	<u>Total (\$)</u>	<u>Cost (\$)</u>	<u>Prof. (%)</u>
TOMA-HAWK	2/17/15	FFF	300	FLUR/BACL/CYCL/ GABA/LIDO 20/2/2/6/2% CREAM	3,608.72	168.99	95.32
ROBU-STO	2/17/15	GG G	240	FLUR/LOPE/ CLON/CYCL/BUPI/ DMSO/MENT 20/5/	3,130.41	209.16	93.32
TOP TIER	2/17/15	HH H	240	FLUR/GABA/BACL /CYCL/BUPI 20/10/2/3/2 % CREA	3,587.49	213.89	94.04
MARV.	2/17/15	III	360	FLUR/BACL/CYCL/ GABA/LIDO 20/4/2/10/5% CREA	5,247.63	254.95	95.14
TOP TIER	2/27/15	JJJ	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/4%	10,508.80	1,061.38	89.90
TOP TIER	3/11/15	KK K	240	FLUR/GABA/BACL /CYCL/BUPI 20/10/2/3/2 % CREA	3,651.04	145.42	96.02
ROBU-STO	3/13/15	LLL	240	FLUR/LOPE/ CLON/CYCL/BUPI/ DMSO/MENT 20/5/	3,130.48	209.16	93.32
ROBU-STO	3/17/15	XX	60	FLUT/LEVO/ PRIL/GABA 1/2/0.5/3/15% GEL	3,061.26	137.74	95.50
CV MCD.	3/20/15	QQ	360	FLUR/BACL/CYCL/ GABA/BUPI 20/4/2/6/3% CREAM	3,790.97	230.08	93.93
TOP TIER	3/23/15	MM M	240	FLUT/TRAN/LEVO/ PENT/GABA/BUPI 1/2/2/2/6/4%	11,453.61	1,061.38	90.73

137. Each of the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) listed in the chart knowingly caused to be submitted the representative examples of false claims to Tricare or other Government insurance programs, and they also knowingly caused to be submitted other

similar false claims to Tricare or other Government insurance programs through Soothe and other pharmacies.

138. The Soothe Defendants knowingly submitted the representative examples of false claims listed in the chart to Tricare or other Government insurance programs, and they also knowingly submitted or caused to be submitted other similar false claims to Tricare or other Government insurance programs directly through Soothe and through other pharmacies via the transfer of prescriptions.

**G. The Defendants Knew or Should Have Known That False Claims Were Submitted.**

139. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
140. Soothe was aware of false representations made by the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) to patients that the products would be provided free or at a minimal cost, as well as many other illegal actions taken by representative groups.
141. While employed at Soothe Plaintiff-Relator attempted to reform the company to a higher standard of compliance, but his efforts to bring Soothe's business into compliance met with resistance at Soothe and from the representative groups.
142. By late 2014 Soothe managers, Defendants Long and DeStefano, considered attempting to comply with the law. Upon minimal attempts to collect co-payments and attempting to get C.V. McDowell and Robusto Enterprises among others to follow basic rules, it became clear that the representative groups such as C.V. McDowell and Robusto Enterprises wanted to continue to do business as they had been doing and use

pharmacies other than Soothe to fill prescriptions as part of the fraudulent scheme to submit false claims to Tricare and other Government payors.

143. Plaintiff-Relator's attempts to persuade Defendants Long and DeStefano to comply with the law included an extensive process of Plaintiff-Relator providing them with specific examples of fraud and false claims, many of which involved patient complaints that could become public and increase Soothe's risk of liability.
144. For example, Plaintiff-Relator forwarded to Defendants Long and DeStefano email correspondence between Soothe and C.V. McDowell dated September 7, 2014. In the emails between C.V. McDowell and Soothe discussed patient complaints about not wanting, needing or requesting the medications and one patient who was threatening to file a fraud complaint. This email correspondence between Soothe and C.V. McDowell included Defendant Jack L. Stapleton, who Plaintiff-Relator mistakenly believed was Jack McDowell, in part because he signed his emails with his first name only.
145. This was hardly the only complaint by a C.V. McDowell customer that pointed to fraud. Plaintiff-Relator informed Soothe and Defendants Long and DeStefano another instance on September 26, 2014 when another patient complained that "C.V. McDowell wouldn't stop calling her about a refill she did not want (she never wanted or requested the first one), for a wound she does not have."
146. Soothe employees conducted a Google search for the phone number provided by the patient from which C.V. McDowell was calling the patient and notified Plaintiff-Relator that it was a "telemarketing number in Boca Raton area, very bad comments on line regarding this number." The employee asked Plaintiff-Relator, "Please, please,

please tell me we aren't using this company.” Plaintiff-Relator shared this information with Defendants Long and DeStefano.

147. On September 29, 2014, Plaintiff-Relator notified by email C.V. McDowell (including Defendant Jack L. Stapleton) and he copied Mr. Long and DeStefano about several wrongful prescription complaints stating, “we have a long list of complaints from week before last that patients were told of no copay but these seem to have stopped.”
148. Mr. Stapleton attempted to assure Plaintiff-Relator that these practices would really end writing back to Mr. Thornton, “moving forward you will see a substantial decline in these complaints due to the internal changes, increased restrictions, and filters that we have implemented for the Soothe campaign starting yesterday.”
149. However, on September 30, Mr. Thornton reported to Defendants Long and DeStefano on two more patients sent from C.V. McDowell, one “was called about some free pain creams. She does not want them.” As to the other patient, “someone called him and said they would send him some free pain cream. He doesn't want it if a copay or billed through his insurance. Also Derek spoke with Dr. Epstein and he is saying he did not sign the” prescriptions.
150. Despite assurances made to Plaintiff-Relator by C.V. McDowell and Soothe that they would comply with the law, these kinds of complaints and issues of fraud did not stop.
151. On or about October 31, 2014, Plaintiff-Relator provided Defendants Long and DeStefano a summary of complaints, including 15 cases of complaints from C.V. McDowell patients almost all of whom were told the prescription would be free despite copayment requirements and many of whom indicated they did not want the

prescription. Consequently, despite being told by Plaintiff-Relator about the fraud and false claims issues, the Defendants continued their practices of submitting or causing to be submitted false claims to Tricare and other Government payors.

152. On November 12, 2014, in advising Defendants Long and DeStefano about a State of Rhode Island inquiry, Plaintiff-Relator noted that not only “Jack McDowell [Stapleton of C.V. McDowell] but many other rep groups” send physicians “pre-printed scripts to sign. It is not only Rhode Island where this is illegal but Jack’s scripts dramatically increase risk because patients don’t want them...”

153. At the time, C.V. McDowell was attempting to interest Soothe in participating in a patient study, which C.V. McDowell claimed would generate many prescriptions to be filled. On November 13, 2014, Sean Hogan of Soothe wrote Plaintiff-Relator and Defendants Long and DeStefano:

Just FYI but I didn’t say we don’t want to participate. We all raised the issue that you can’t say “free” copays but there was no definitive statement like he claims.

Having said that I don’t doubt the study will continue to create the same serious problems.

154. Plaintiff-Relator on seeing this email wrote to Defendants Long and DeStefano stating, “Unfortunately, I concur with Sean’s assessment.”

155. Defendant DeStefano wrote to C.V. McDowell declining to participate in the study on November 13, 2014:

Jack- I’m happy to take your call but we’ve had some huge issues with some of the patients contacting insurance companies and now we are at risk with a major PBM to lose their contract. We also called the Lexington office to see how co-pays or non-coverage would be handled from your study the Response from

the lady in your office again said there will be little or no cost to the patient. That never occurs with our pharmacy. You know Brad and I have a good personal relationship with you and always wish you luck but unfortunately we have made a decision not to proceed. We have too much at risk and we fear we may have lost a contract already.

156. On a conference call with Plaintiff-Relator and representatives of C.V. McDowell including both Jack L and Jack H. Stapleton towards the end of 2014 Mr. Thornton directly addressed the younger Mr. Stapleton. Plaintiff-Relator told the C.V. McDowell officials on the call that their practices were illegal that he feared that they could go to jail, despite Mr. Stapleton's assertion that they were not serious violations.
157. Plaintiff-Relator told Defendants Long and DeStefano he was concerned with C.V. McDowell's false representations that the products were free, that they were medically necessary when the patients had not claimed conditions cited, that they did not have documentation for the products that they generated automatic refills and used pre-printed forms as well as controlling the prescription through having the doctors fax the information back to them instead of directly to the pharmacies.
158. C.V. McDowell showed no inclination to change any of their illegal practices and the Plaintiff-Relator was well aware that C.V. McDowell conducted business similarly with many other pharmacies.
159. Similarly, in March of 2015 Soothe terminated its relationship with Robusto Enterprises in emails with Eddie Lopez.
160. In an email from Defendant DeStefano to Defendant Lopez on March 19, 2015, he was careful to say, "This isn't meant as anything derogatory toward your team. Mutually

we know you are moving the business in a different direction that made more sense for you and Soothe. That's ok.”

161. Despite having severed their relationship with C.V. McDowell in the Fall of 2014 and with Robusto Enterprises in March of 2015, Soothe had knowingly participated with the Defendants-representative groups to submit millions of dollars of false claims.
162. Even at that time Soothe was reluctant to handle these matters forthrightly and still attempted to profit illegally. Mr. Thornton made note of an incident as late as March 12, 2015 when DeStefano was over-ruling him with another Soothe employee. That employee was told by Mr. DeStefano to send out a refill prescription for which, there had been no copayment collected. DeStefano apparently told the other Soothe employee to go forward and Mr. DeStefano would take the heat from Mr. Thornton.
163. In any event at no time did the Soothe Defendants or Mr. Long or Mr. DeStefano notify any government official of any of the illegal practices conducted by Robusto Enterprises, C.V. McDowell or any of the representative groups despite Soothe's clear knowledge of the fraud scheme and that false claims had been submitted to the Government.
164. Despite ending the relationship formally in March of 2015, Soothe continued to fill refill prescriptions from Robusto Enterprises.
165. Despite being told by Soothe that there were concerns about fraud or other violations neither the Robusto Defendants nor the C.V. McDowell Defendants stopped causing false claims to be submitted, and they in fact continued working with other pharmacies



to continue the fraud to submit false claims, and nor did either the Robusto Enterprises Defendants or the C.V. McDowell Defendants notify the Government about the fraud.

## **VIOLATIONS OF THE FALSE CLAIMS ACT**

### **COUNT I**

#### **(Violations of 31 U.S.C. § 3729(a)(1)(A), Submitting and or causing the submission of False Claims to the United States)**

166. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
167. This is an action for treble damages and civil penalties under the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A).
168. As demonstrated above, the Defendants submitted or caused false claims to be submitted to the United States in violation of 31 U.S.C. § 3729(a)(1)(A).
169. Defendants created such false claims through the illegal transfer of prescriptions en masse in exchange for a percentage of the transferred prescription, the waiver, reduction or arrangement for the reduction of co-payments owed by patients in violation of the Anti-Kickback Statute (“AKS”) and government regulations.
170. In addition, the representative groups (including but not limited to the C.V. McDowell Defendants and the Robusto Enterprises Defendants) routinely obtained a commission for prescriptions they arrange to be filled by the pharmacies creating an illegal kickback scheme in violation of the AKS.
171. The Defendants misrepresented the need for such prescriptions to physicians undermining the requirement that such prescriptions be medically necessary. They misrepresented co-payment obligations to patients who upon learning they are liable for such co-payments may determine the medicine is not, in fact, necessary.

172. The Defendants routinely use pre-printed prescription pads to further their goals including using these forms to create automatic refills of prescriptions. The Defendants promoted specific prescriptions solely to increase the cost of the prescriptions. Even when such forms and automatic refills are allowed, the defendants filled them pursuant to a scheme to avoid having the patient make a co-payment and other illegal remuneration schemes rather than to serve a patient's medical need.
173. The Robusto Enterprises Defendants and the C.V. McDowell Defendants, respectively, sent prescriptions to doctors' offices and had them returned to them and then sent these prescriptions to pharmacies, who fill the prescription. Such a procedure explicitly indicates the prescription did not come directly from the doctor's office, which should be, in and of itself, a cause for enough concern not to fill the prescription and bill the Government. All parties knew or should have known the major purpose of this activity is so that the Robusto Enterprises Defendants and the C.V. McDowell Defendants, respectively, can be sure to obtain commissions on the sale as part of their kickback arrangements that caused the submission of false claims to the Government by Soothe and other pharmacies.
174. The Soothe Defendants did not maintain efforts to ensure that the prescribing doctor comported with the laws of the state in which the prescription was filled despite acting as national providers of these pharmaceuticals.
175. Through the above practices the Defendants submitted or cause to be submitted false claims to the United States and are liable for three times the amount of damages created by such false claims made to the government of the United States.

176. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of Five Thousand, Five Hundred Dollars to Eleven Thousand Dollars (\$5,500-\$11,000), plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

**COUNT II**

**(Violations of 31 U.S.C. § 3729(a)(1)(B),  
Using False Statements)**

177. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
178. In furtherance of the illegal activities described herein Defendants necessarily created false records material to supporting false claims in violation of 31 U.S.C. § 3729(a)(1)(B).
179. Each and every prescription created as a result of the Defendants' illegal practices to increase revenue such as waiving co-payments and transferring prescriptions creates a false record material to obtaining payment from a government program.
180. The Defendants are liable for three times the amount of damages created by such false claims made to the government of the United States.
181. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of Five Thousand, Five Hundred Dollars to Eleven Thousand Dollars (\$5,500-\$11,000), plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

**COUNT III**

**(Violations of 31 U.S.C. § 3729(a)(1)(C),  
Conspiring to submit False Claims)**

182. The allegations in the paragraphs above are hereby re-alleged as set forth fully above.
183. Each of the representative groups separately agreed to work with Soothe and other pharmacies to fill prescriptions in a conspiracy to submit or cause to be submitted false claims to obtain payments from government programs in violation of 31 U.S.C. § 3729(a)(1)(C). For example, the C.V. McDowell Defendants conspired with Soothe and other pharmacies to submit false claims to Tricare and other Government programs. Additionally, the Robusto Enterprises Defendants separately conspired with Soothe and other pharmacies to submit false claims to Tricare and other Government programs.
184. The Defendants are jointly and severally liable for three times the amount of damages created by such false claims that they conspired to submit or caused to be submitted to the government of the United States.
185. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of Five Thousand, Five Hundred Dollars to Eleven Thousand Dollars (\$5,500-\$11,000), plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

**COUNT IV**

**(Violations of the False Claims Act 31 U.S.C. § 3729 (a)(1)(G), Reverse False Claims)**

186. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

187. Defendants violated Section 3729(a)(1)(G) of the False Claims Act, as amended. As set forth above, Defendants knowingly made, used or caused to be made or used a false record or statement material to an obligation to pay or transmit funds to the Government improperly obtained for federal funding, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.
188. Defendants knowingly made false statements and false certifications with full knowledge that these false statements and false certifications would be material to the United States' decision to pay.
189. As a direct and proximate result of Defendants' fraudulent and illegal actions and pattern of fraudulent conduct, the United States has paid directly or indirectly scores of false claims and spent millions of dollars.
190. By reason of Defendants' false or fraudulent claims, the United States has been damaged in a substantial amount to be determined at trial.
191. Damages to the United States include, but are not limited to, the full amount it has paid on any such fraudulent claims and any related obligations of Defendants to pay or transmit money to the Government. Defendants are liable to the United States for three times the full amount of these damages, plus interest.
192. Each and every such violation is also subject to a civil fine under the False Claims Act of five thousand five hundred to eleven thousand dollars (\$5,500 - \$11,000), plus any increase as specified by the Federal Civil Penalties Inflation Adjustment Act of 1990.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff-Relator, on behalf of himself, and the United States requests that judgment be entered in his favor and against Defendants as follows:

- (a) That Defendants cease and desist from violating 31 U.S.C. § 3729, *et seq*;
- (b) That this Court enter judgment against all Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- (c) That Plaintiff-Relator be awarded an amount that the Court decides is reasonable, which shall not be less than 15% nor more than 30% of the proceeds or settlement of any related administrative, criminal, or civil actions, including the monetary value of any equitable relief, fines, restitution, or disgorgement to the United States, and/or third parties;
- (d) That Plaintiff-Relator be granted a trial by jury;
- (e) That Plaintiff-Relator, and the United States be awarded pre-judgment interest;
- (f) That the Plaintiff-Relator, be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. §§ 3730(d).
- (g) The United States, and the Plaintiff-Relator recover such other relief as the Court deems just and proper.

**JURY TRIAL DEMANDED**

Plaintiff-Relator requests a trial by jury on all counts.

Respectfully submitted,

/s/ Anthony C. Munter

Anthony C. Munter, Trial Counsel  
PRICE BENOWITZ, LLP  
409 7th Street, N.W.  
Washington, DC 20004  
Phone: 202-417-6000  
Fax: 202-664-1331  
Email: tony@pricebenowitz.com  
Admitted *Pro Hac Vice*

/s/ David K. Colapinto

David K. Colapinto, Trial Counsel  
KOHN, KOHN & COLAPINTO, LLP  
3233 P Street, N.W.  
Washington, D.C. 20007-2756  
Phone: 202-342-6980  
Fax: 202-342-6984  
Email: dc@kkc.com  
Admitted *Pro Hac Vice*

/s/ Charles C. Campbell

Charles C. Campbell  
Florida Bar No.: 0084927  
CAMPBELL LAW P.A.  
4106 N US Highway 1  
Melbourne, FL 32935  
Phone: 407.900.4004  
Fax: 407.477.4144  
Email: charles@campbellpa.com

Attorneys for Plaintiff-Relator

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a copy of the foregoing Second Amended Complaint was served on this 23rd day of May, 2018, upon all counsel registered via the Court's ECF system.

By: /s/ David K. Colapinto  
David K. Colapinto