

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BN

UNITED STATES OF AMERICA;
STATE OF CALIFORNIA; STATE
OF COLORADO; STATE OF
CONNECTICUT; STATE OF
DELAWARE; STATE OF FLORIDA;
STATE OF GEORGIA; STATE OF
HAWAII; STATE OF ILLINOIS; STATE
OF INDIANA; STATE OF IOWA; STATE
OF LOUISIANA; STATE OF MARYLAND;
COMMONWEALTH OF MASSACHUSETTS;
STATE OF MICHIGAN; STATE OF
MINNESOTA; STATE OF MONTANA;
STATE OF NEVADA;
STATE OF NEW JERSEY;
STATE OF NEW MEXICO; STATE OF NEW
YORK; STATE OF NORTH CAROLINA;
STATE OF OKLAHOMA; STATE OF
RHODE ISLAND; STATE OF TENNESSEE;
STATE OF TEXAS; COMMONWEALTH OF
VIRGINIA; STATE OF WASHINGTON;
STATE OF WISCONSIN; and THE DISTRICT
OF COLUMBIA
ex rel. HEATHER MURRAY,

CASE NO.:

8:16 cv 226 T30 JSS

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

Plaintiffs,

v.

GRIFOLS USA, LLC
GRIFOLS BIOLOGICALS, INC.,
GRIFOLS, S.A.,
GRIFOLS, INC.,

Defendants.

QUI TAM COMPLAINT

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INTRODUCTION

1) Government healthcare programs such as Medicare and Medicaid tightly restrict the types and uses of drugs eligible for purchase using federal and state funds. Federal regulations further prohibit drug companies from marketing practices which could lead to unnecessary or ineffective prescription of drugs. These regulations are intended to insure that government funds are used only to purchase drugs that have been determined to be safe and effective for treatment of specific conditions.

2) Relator Heather Murray alleges in this qui tam action that Defendants have undertaken a blatant and purposeful course of action designed to push its anti-thrombin concentrate drug, Thrombate III, into markets for which it has not been approved for use. Thrombate III, an orphan drug, has a specific indication—it is approved for use in patients with hereditary anti-thrombin III deficiency, a condition which affects a very small portion of the population. However, Grifols developed a strategic plan to promote Thrombate III in markets beyond the drug's approved indication, using its sales force to improperly target pediatric patients and patients with acquired anti-thrombin III deficiency.

3) Not only has Thrombate III not been evaluated for use in patients under the age of 16, the drug is potentially harmful for children and may have caused brain hemorrhaging in infants who were patients in pediatric hospitals that Grifols markets to. Regardless of these facts, nearly half of Grifols's marketing efforts are to pediatric hospitals and physicians. Pediatric hospitals appear on the call-lists distributed by Grifols to its sales force. Grifols also promotes Thrombate III for patients with acquired anti-thrombin III deficiency (as opposed to patients with hereditary anti-thrombin deficiency, for whom the drug was approved), and it has an incredible incentive to do so-- Thrombate III is nearly ten times more expensive than the alternative

treatment for the condition. Consequently, Defendants' intentional off-label marketing practice has caused its corporate revenues to soar, but it has also opened the door for potential harm to pediatric patients, and has caused significant financial harm to the government.

4) Relator has both personal and inside knowledge of Defendants' corporate endorsement of its national off-label marketing scheme of Thrombate III. Relator is an original source as defined by the False Claims Act in 31 U.S.C. § 3730(e)(4)(B) and has made voluntary disclosures to the United States prior to the filing of this lawsuit.

PARTIES

5) Relator Heather Murray ("Relator") is a citizen of the Commonwealth of Pennsylvania. She has been a pharmaceutical sales representative since 2005. In 2010, Relator was hired as a pharmaceutical representative for Talecris BioTherapeutics ("Talecris"). Since 2011, Relator has been employed by Defendant Grifols USA, LLC in its Bioscience Division. Throughout her employment with Grifols USA, LLC, she has been assigned to the thrombosis sales team as a sales representative. She currently markets Thrombate III to dozens of hospitals in Pennsylvania, New Jersey and Delaware. Relator also obtained a Bachelor of Science degree in Nursing in 2013.

6) Defendant Grifols USA, LLC is a subsidiary of Defendant Grifols, S.A. Grifols USA, LLC manufactures, markets and/or distributes more than 21 drugs in the United States. It is headquartered in Los Angeles, California.

7) Defendant Grifols Biologicals Inc. is a wholly owned subsidiary of Defendant Grifols Inc. In 2010, Grifols, Biologicals, Inc. purchased Talecris Biotherapeutics for \$3.4 billion. The company was incorporated in 2003 and is based in Los Angeles, California.

8) Defendant Grifols, S.A. is headquartered in Barcelona, Spain and is a major world supplier of plasma-derived products. Its 2014 revenue was 3.3 billion euros, more than \$2 billion of which was attributed to its North American sales. It has been listed on the Madrid Stock Exchange since 2006 and employs more than 11,000 people.

9) Defendant Grifols Inc. is a Delaware corporation and a wholly owned subsidiary of Defendant Grifols S.A..

10) All Defendants named in this Complaint will henceforth be collectively referred to as "Grifols" or "Defendants."

JURISDICTION AND VENUE

11) This action arises under the False Claims Act, 31 U.S.C. § 3729 et seq. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 31 U.S.C. § 3730, and 28 U.S.C. § 1345. This Court has jurisdiction over the State False Claims Act claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

12) This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Defendants can be found in, reside in, or have transacted business in the Middle District of Florida.

13) Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in, reside in, or have transacted business in the Middle District of Florida, and many of the alleged acts occurred in this District.

REGULATORY BACKGROUND

14) Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its

intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

15) To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

16) Pharmaceutical drugs cannot be sold in the United States until the Food and Drug Administration ("FDA") has concluded that a drug is safe and effective at specific dosages. The FDA-approved indications and dosages are set forth on an approved drug's label. Physicians may prescribe FDA-approved drugs for indications, or at dosages, that vary from those set forth on the label, but drug companies are prohibited under the Food, Drug, and Cosmetic Act from marketing or promoting approved drugs for uses other than the approved uses set forth on the label. 21 U.S.C. § 355(a) & (d). Distribution of prescription drugs for off-label uses is expressly prohibited. 21 U.S.C. § 331(d).

17) FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels—including all marketing and promotional materials relating to the drug—may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

18) The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict

scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

19) A manufacturer wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 et seq. A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

20) "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, e.g., treating a child when the drug is approved to treat adults.

21) Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This

includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on, or off, label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug Company sponsored continuing medical education ("CME") courses and speaker programs, and drug Company sponsored clinical trials.

22) Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. § 202.1 (e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

23) Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described below.

24) Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331 (a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

25) Federal anti-kickback laws, 42 U.S.C. § 1320a-7b(b), also regulate the marketing of pharmaceuticals to prevent overutilization of prescription drugs. Drug companies are prohibited from offering or paying remuneration, cash or otherwise, to induce physicians or others to recommend or prescribe drugs that may be paid for by federal programs such as Medicaid or Medicare. 42 U.S.C. § 1320a-7b(b). Improper and illegal inducements include payment of "research grants," paying physicians for "studies," or any payments that are based on the volume of prescriptions written.

26) Additionally, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Govt. Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia False Medicaid Claims Act, 49 Ga. Code Ann. Ch. 4 at 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12 § 5A *et seq.*, Montana False Claims Act, Mont. Code Ann. § 17-8-4031. *et seq.*, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*, New Mexico Medicaid False Claims Act,

N.M. Stat. Ann. § 27-14-4 *et seq.*, New Jersey False Claims Act, N.J.S.A. §2A:32C *et seq.*, New York False Claims Act, N.Y. State Fin. Law § 189 *et seq.*, Oklahoma Medicaid False Claims Act § 63-5053.1 *et seq.*, Rhode Island State False Claims Act 9-1.1-3 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

DEFENDANTS' FRAUDULENT CONDUCT

27) Antithrombin is a protein molecule produced by the liver which inactivates several enzymes of the coagulation system. Antithrombin, also referred to as "Antithrombin III" or "AT III," accounts for a large percentage of the body's natural anticoagulant.

28) Thrombate III is an orphan drug indicated solely for the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism. Hereditary antithrombin deficiency is an extremely rare condition, affecting no more than 5,000 total patients in the general population.

29) Thrombate III is listed on the Medicare formulary and the formularies of Medicaid programs, including that of the University of Florida's Shands Hospital.

30) Defendants have exclusive rights to manufacture and market Thrombate III. The drug costs \$4.30 per international unit ("IU") and costs for individual vials range from \$1,800 to \$2,500. The average cost of Thrombate III treatment is \$22,666.

31) Relator has been a pharmaceutical sales representative for more than a decade. In 2010, she began working for Talecris Biotherapeutics ("Talecris"), which manufactured and sold Thrombate III.

32) While Relator was employed as a sales representative for Talecris, the company marketed the drug off-label for use in coronary pulmonary bypass (“CPB”), open heart surgery and acquired anti-thrombin III deficiency patients.

**Grifols Purchases Talecris and Begins Off-Label Marketing
For Use in Children to Boost Profits**

33) On June 2, 2011, Defendant Grifols USA, LLC., a subsidiary of Defendant Grifols S.A., purchased Talecris. Because of the paucity of potential patients with hereditary anti-thrombin III deficiency and the high cost of Thrombate III treatments, Defendants determined that it was too unprofitable to confine sales solely to on-label indications. As a result, Defendants decided to cast a wider net, and began marketing Thrombate III for off-label use in potential pediatric patients in addition to the off-label uses previously marketed by Talecris.

34) Soon after Defendants purchased Talecris, Grifols (through its twenty-six (26) pharmaceutical sales representatives) continued to market Thrombate III off-label as before, but also marketed it to hospitals and physicians who treat pediatric Extracorporeal Membrane Oxygenation (“ECMO”¹) patients. Almost immediately after it acquired Talecris, Defendants issued “call-lists” to Relator and other sales representatives which continued to include hospital departments that would ordinarily not treat hereditary anti-thrombin III deficiency, but for the first time also included pediatric hospitals which treated ECMO patients.

35) Since 2011, Grifols’s sales representatives, including Relator, have been required to follow a national sales policy and procedure directed at promoting the off-label use of Thrombate III. Grifols has known that its off-label marketing scheme would result in hospitals and physicians submitting false claims to Medicare and Medicaid for reimbursement of off-label

¹ ECMO is a procedure used to circulate blood through an artificial lung back into a baby’s bloodstream.

uses of Thrombate III. As a result of this off-label marketing scheme, hundreds of hospitals and physicians nationwide have submitted false claims to Medicare and Medicaid seeking reimbursement for off-label Thrombate III uses.

36) Relator currently markets to twenty-five (25) target hospitals in Pennsylvania, New Jersey, Maryland and Delaware, four of which are pediatric hospitals. Relator's sales quotas have consistently far exceeded those commensurate with on-label sales. Relator has learned that Grifols also markets to a number of hospitals in Florida, including All Children's Hospital and Florida Hospital Orlando, both of which are located in the Middle District of Florida.

37) Defendants' scheme to boost its profits by expanding its fraudulent off-label marketing efforts has dramatically increased its revenues. Relator estimates that, since Defendants broadened the scope of its off-label marketing of Thrombate III, more than 90% of its sales have been off-label. As noted above (§ 30, *supra*), empirical studies indicate that the average course of Thrombate III treatment costs in excess of \$22,000, and some costs exceed \$60,000. Relator has reviewed recent sales figures which show that Thrombate III sales are rapidly increasing and generated in excess of \$50 million in revenue in 2014 and over \$200 million in the last six (6) years. A large percentage of sales of Thrombate III in the United States are reimbursed by government healthcare programs.

Thrombate III is Not Approved for Use on Children and Possibly Harms Them

38) Clinical studies have noted both the increased off-label use of antithrombin treatments and the lack of support establishing its safety or efficacy in use on critically-ill children. One 2006 study of the use of antithrombin treatments such as Thrombate III, in

preterm infants concluded that not only were infants with respiratory distress syndrome unlikely to benefit from antithrombin treatment, the treatment may actually harm them.

39) Similarly, in November 2013, the National Institute of Health (“NIH”) conducted a study of antithrombin use for children and found a significant increase in off-label use of Thrombate III for critically-ill children receiving ECMO. The study further concluded that the safety and efficacy of antithrombin concentrations in pediatrics has not been established and that, as such, Thrombate III is not FDA approved in this population. Critically, the NIH study also found that subjects who receive Thrombate III had a “statistically significant 1.5-fold greater risk of bleeding” and that this was likely attributable “to higher circulating levels of this anticoagulant.”

40) In October 2013 Relator was contacted by the ECMO coordinator at the Alfred I. Dupont Hospital for Children in Delaware who advised he was aware of two (2) neonatal patients who suffered brain hemorrhages after being treated with Thrombate III. Relator filed an Adverse Event report with Grifols regarding this inquiry but is unaware of what action, if any, was taken.

Grifols is Aware of, and Supports, the Off-Label Marketing of Thrombate III

41) Grifols has full knowledge that its pharmaceutical representatives are engaging in fraudulent, off-label marketing of Thrombate III. Indeed, company executives have directed Relator to engage in the off-label marketing, and in some cases, have paid for off-label marketing expenses.

42) As noted above, Grifols generated call-lists which included pediatric hospitals and hospital departments that would rarely—if ever—treat hereditary antithrombin III deficiency. The call-lists are approved by Grifols executives, including the National Director of Marketing

Operations, Andrew DiDomenico; the National Marketing Director for Hematology, Marcie Porter; the Vice President of Sales and Marketing, Keith Arbuckle; and the Senior Director for National Sales, Hematology, Diane Lahay. All four work at Grifols's management facility in Raleigh, North Carolina.

43) In addition, Grifols purchased a display booth at a national conference conducted by the Extracorporeal Life Support Organization and assigned Relator to the booth to display graphics pertaining to the use of Thrombate III for neonatal ECMO patients. Reimbursement for the expenses associated with this display booth were approved by Lisa Latu, the administrative associate for several of Grifols's national executives.

44) Grifols also regularly uses physicians to promote the off-label use of Thrombate III. For example, Dr. Michael D. Tarantino, a pediatric hematologist, and Dr. Stephen Bader, a cardiac anesthesiologist, along with eight (8) other physicians, comprise the Promotional Speaker Bureau for Thrombate III. Grifols often uses Dr. Tarantino to give presentations regarding the use of Thrombate III to ECMO and cardiac units at various hospitals across the country.

45) Additionally, in August 2012, at a training session in North Carolina, Dr. Bader made a slide presentation regarding the off-label use of Thrombate III to treat acquired anti-Thrombin III deficiency. Grifols reimbursed Dr. Bader's expenses.

46) In 2013, at the direction of her regional supervisor, Mike Graham, Relator created a Power Point presentation showcasing the use of antithrombin in ECMO procedures. This presentation was displayed at a sales force workshop attended by Mr. Graham and six (6) Grifols sales representatives from the northeast sales region. Notably, in a June 4, 2013 email memorializing the workshop, Mr. Graham recounted the covered topics but intentionally omitted

Relator's Power Point presentation, signaling to Relator that Grifols is fully aware that off-label marketing Thrombate III for use in ECMO procedures is unlawful.

47) On October 6, 2015, Relator attended a regional sales meeting in Boston, Massachusetts. Present at this meeting was Diane Lahay, Grifols's Senior Director for National Sales, Hematology. Lahay instructed Relator and other sales representatives to begin marketing Thrombate III off-label to hospital orthopedic units. When Relator expressed her concerns that this marketing practice was improper, Lahay asked Relator if she was comfortable marketing Thrombate III to anesthesiology and ECMO units. When Relator explained that she was not comfortable marketing to these groups, Lahay told her: "It is your job to go into those areas."

48) Because of Lahay's position as a national sales director, this regional sales meeting confirmed for Relator that the decision to market Thrombate III to ECMO units was made at the highest levels of Grifols's corporate structure.

49) Grifols is also providing physicians with information concerning Thrombate III which directly contradicts the FDA-approved language provided on the drug's package insert. Thrombate III must be reconstituted before use, and the package insert for Thrombate III states it should be used within three hours of reconstitution. However, many cardiac and ECMO physicians prefer to continuously infuse post-operative patients with Thrombate III for a period of forty-eight hours. To assuage their concerns regarding this disparity, Grifols routinely issues those physicians a letter advising that, contrary to the information provided in the FDA-approved package insert, studies conducted by Grifols show Thrombate III is safe for use over a forty-eight hour period.

**Grifols has Caused, and is Causing, False Claims to be Submitted
to Government Healthcare Programs**

50) Grifols's "off-label" promotional activities constitute false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 331(a) and (b), 352(a) and (t) and regulations promulgated by the FDA to implement the FDCA.

51) Moreover, Grifols has knowledge that its unlawful off-label marketing efforts would cause healthcare providers to submit claims for reimbursement by government healthcare providers.

52) In addition to compliance with other national or state coverage criteria, government healthcare programs require, as a condition of coverage, that services be reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services and provide them only when medically necessary. 42 U.S.C. § 1320c-(a)(1).

53) The off-label use of Thrombate III results in claims being submitted to government healthcare programs for medically unnecessary services. By unlawfully marketing Thrombate III off-label to hospitals and physicians, Grifols is, therefore, knowingly causing false claims to be submitted to Government Healthcare Programs.

54) The United States and state Medicaid programs, unaware of the falsity of the claims and/or statements which Grifols caused health care providers to make to the United States and state Medicaid programs, and in reliance on the accuracy thereof, paid health care providers for claims that would otherwise not have been allowed.

55) The coding, billing and reimbursement procedures applicable to Thrombate III deviate from several of the standard procedures associated with other drugs.

56) The majority of the patients who receive Thrombate III are administered this drug in the inpatient setting. Under CMS's Acute Care Hospital Inpatient Prospective Payment System (IPPS), the HCPCS code for "Antithrombin III injection" is J7197. Thrombate III falls

under the J code section of the HCPCS Level II codes because it is an injectable drug. (J-codes are defined as non-orally administered medication and chemotherapy drugs.)

57) In connection with the use of certain types of drugs, a hospital may receive “pass through payments,” which are made to the hospital in addition to DRG and any outlier payments and currently equal the Average Sales Price (ASP) of the drug plus 6%. In order to receive a pass through payment from Medicare for an eligible drug, a hospital must report the relevant J code along with Revenue Code 0636 on the inpatient claim. The claim must also contain a qualifying diagnosis code. Certain hospitals may be utilizing pass through payments to receive reimbursement for the administration of Thrombate III to their patients. Pass through payments for the use of Thrombate III in connection with procedures, such as ECMO, are improper because, as described above, these procedures involve off-label uses of this drug.

58) On information and belief, certain hospitals do not report the J code on the inpatient claim when Thrombate III is administered to a patient. In these cases, either Revenue Code 0636 or Revenue Code 250 is listed but there is no J code reported. Even if a hospital “hides” the drug charge in a drug charge line item on an inpatient claim, the use of Thrombate III, can still be identified by looking at individual patient itemized bills (IB). An itemized bill details charges for a patient encounter that are charged from and correspond to the hospital’s chargemaster.

59) The hospital chargemaster is a repository of all drugs, supplies and services that may be rendered to a patient. This database usually consists of a cost center identification (e.g. Department), type of service code (revenue code), unique charge code (chargemaster #), the corresponding CPT/HCPCS code (if applicable), and charge for the line item. Additional elements may be General Ledger number and modifiers. The patient itemized bill is compiled

from charges occurring during a single encounter and would contain a record of every drug that is administered to that patient.

60) Even if a hospital does not report the J code and/or does not request a pass through payment, Medicare damages can still be incurred for the off-label use of Thrombate III due to the relatively high cost of the drug. For example, an improper charge for Thrombate III can increase the overall charges which may trigger an outlier payment that Medicare pays hospitals in addition to the DRG reimbursement amount. In some instances the charge for Thrombate III may be significant enough to push a claim into outlier status. In these cases, the hospital would have received a DRG payment only (as opposed to a DRG plus outlier payment) if the improper charge for Thrombate III had not been included on the inpatient claim.

61) With regard to the calculation of Medicaid damages, the reimbursement mechanisms differ from state to state. Certain states utilize a system in which outlier payments are made in addition to the APR-DRG reimbursement in a manner analogous to the Medicare outlier payments described in the previous paragraph. Some states, such as California, employ an Average Sales Price blood factor reimbursement method akin to the Medicare pass through payments, as well as outlier payments, which can be triggered by certain drug charge line items.

62) Defendants' off-label marketing practices have not only threatened patient safety, but also, as described above, have resulted in monetary damages to government healthcare programs.

COUNT I

VIOLATION OF FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3729-33

63) Relator realleges and incorporates by reference paragraphs 1 through 62 as though fully set forth herein.

64) This is a civil action brought by Relator on behalf of the United States against Defendants under the Federal False Claims Act, 31 U.S.C. § 3729-33.

65) Under the False Claims Act, 31 U.S.C. § 3729(a), in effect prior to May 20, 2009, Defendants have violated:

- i. 31 U.S.C. § 3729(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; and/or
- ii. 31 U.S.C. § 3729(a)(2) by knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim allowed or paid or approved by the Government.

66) Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated:

- i. 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval; and/or
- ii. 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

67) Government Payors, unaware of the falsity of the claims and/or statements made or caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for purported medical services performed for patients insured by federally-funded health insurance programs, including Medicare, Medicaid and CHAMPUS/TRICARE. Had the United States known that the bills presented by Defendants were false and/or fraudulent, payment would not have been made for such claims.

68) Defendants' unlawful conduct is continuing in nature and has caused the United States to suffer damages.

COUNT II

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

69) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

70) Through the acts described above, Defendants intentionally and knowingly failed to remit funds paid by Government Payors for the off-label use of Thrombate III.

71) Under the False Claims Act, 31 U.S.C. § 3729(a), in effect prior to May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

72) Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(1)(G) by 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, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

73) Defendants' fraudulent concealment and intentional failure to report funds that were improperly received from Government Payors for the off-label use of Thrombate III by Defendants constitutes an unlawful avoidance of an obligation to pay money owed to the United States.

74) Defendants' unlawful conduct is continuing in nature and has caused the United States to suffer damages.

COUNT III

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT Cal. Govt. Code § 12651, *et seq.*

75) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

76) This count sets forth claims for treble damages and forfeitures under the California False Claims Act.

77) Through the acts described above, Defendants knowingly caused to be presented to the California Medicaid Program fraudulent claims, records, and statements.

78) Defendants knowingly violated:

- i. Cal. Govt. Code § 12651(a)(1) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. Cal. Govt. Code § 12651(a)(2) by knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; and/or
- iii. Cal. Govt. Code § 12651(a)(7) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

79) The State of California, unaware of the falsity of the claims, approved, paid and participated in payments made by the California Medicaid Program for claims that otherwise would not have been allowed.

80) Defendants' unlawful conduct is continuing in nature and has caused the State of California to suffer damages.

COUNT IV

**VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT
Col. Rev. Stat. § 12.25.5-4-305, *et seq.***

81) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

82) This count sets forth claims for treble damages and forfeitures under the Colorado Medicaid False Claims Act.

83) Through the acts described above, Defendants knowingly caused to be presented to the Colorado Medicaid Program fraudulent claims, records and statements.

84) Defendants knowingly violated:

- i. Col. Rev. Stat. § 12.25.5-4-305(a) by knowingly presenting, or causing to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
- ii. Col. Rev. Stat. § 12.25.5-4-305(b) by knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; and/or
- iii. Col. Rev. Stat. § 12.25.5-4-305(f) by 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 state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or

decreases an obligation to pay or transmit money or property to the state in connection with the “Colorado Medical Assistance Act.”

85) Defendants knowingly presented false claims for payment to the State of Colorado. The State of Colorado, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Colorado Medicaid Program for claims that otherwise would not have been allowed.

86) Defendants’ unlawful conduct is continuing in nature and has caused the State of Colorado to suffer damages.

COUNT V

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT Ct. P.A. 09-5 § 17b-301, *et seq.*

87) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

88) This count sets forth claims for treble damages and forfeitures under the Connecticut False Claims Act.

89) Through the acts described above, Defendants knowingly caused to be presented to the Connecticut Medicaid Program fraudulent claims, records, and statements.

90) Defendants knowingly violated:

- i. Ct. P.A. 09-5 § 17b-301b(1) by knowingly presenting, or causing to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;
- ii. Ct. P.A. 09-5 § 17b-301b(2) by knowingly making, using, or causing to be made or used, a false record or statement to secure the payment or approval by the state

of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services; and/or

- iii. Ct. P.A. 09-5 § 17b-301b(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services.

91) Defendants knowingly presented false claims for payment to the State of Connecticut. The State of Connecticut, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Connecticut Medicaid Program for claims that otherwise would not have been allowed.

92) Defendants' unlawful conduct is continuing in nature and has caused the State of Connecticut to suffer damages.

COUNT VI

VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT 77 Del. Laws c. 166 § 1201, *et seq.*

93) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

94) This count sets forth claims for treble damages and forfeitures under the Delaware False Claims and Reporting Act.

95) Through the acts described above, Defendants knowingly caused to be presented to the Delaware Medicaid Program fraudulent claims, records, and statements.

96) Defendants knowingly violated:

- i. 77 Del. Laws c. 166 § 1201(a)(1) by knowingly presenting, or causing to be presented to an officer or employee of the Government a false or fraudulent claim for payment or approval;
- ii. 77 Del. Laws c. 166 § 1201(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government; and/or
- iii. 77 Del. Law 66 § 1201(a)(7) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

97) Defendants knowingly presented false claims for payment to the State of Delaware. The State of Delaware, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Delaware Medicaid Program for claims that otherwise would not have been allowed.

98) Defendants' unlawful conduct is continuing in nature and has caused the State of Delaware to suffer damages.

COUNT VII

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT Fla. Stat. § 68.082, *et seq.*

99) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

100) This count sets forth claims for treble damages and forfeitures under the Florida False Claims Act.

101) Through the acts described above, Defendants knowingly caused to be presented to the Florida Medicaid Program fraudulent claims, records, and statements.

102) Defendants knowingly violated:

- i. Fla. Stat. § 68.082(2)(a) by knowingly presenting, or causing to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
- ii. Fla. Stat. § 68.082(2)(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim allowed or paid; and/or
- iii. Fla. Stat. § 68.082(2)(g) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency.

103) Defendants knowingly presented false claims for payment to the State of Florida.

104) The State of Florida, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Florida Medicaid Program for claims that otherwise would not have been allowed.

105) Defendants' unlawful conduct is continuing in nature and has caused the State of Florida to suffer damages.

COUNT VIII

VIOLATION OF THE GEORGIA TAXPAYER PROTECTION FALSE CLAIMS ACT O.G.C.A. 23-3-121, *et seq.*

106) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

107) This count sets forth claims for treble damages and forfeitures under the Georgia Taxpayer Protection False Claims Act (prior to July 1, 2012, the Georgia False Medicaid Claims Act, O.G.C.A. 49-4-186, *et seq.*).

108) Through the acts described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program fraudulent claims, records, and statements.

109) Defendants knowingly violated:

- i. O.G.C.A. 23-3-121(a)(1) by knowingly presented or causing to be presented a fraudulent claim for payment or approval;
- ii. O.G.C.A. 23-3-121(a)(2) by knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; and/or
- iii. O.G.C.A. 23-3-121(a)(7) by 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 state or local government, or knowingly concealing, knowingly or improperly avoiding, or decreasing an obligation to pay or transmit money or property to the state or a local government.

110) Defendants knowingly presented false claims for payment to the State of Georgia. The State of Georgia, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Georgia Medicaid Program for claims that otherwise would not have been allowed.

111) Defendants' unlawful conduct is continuing in nature and has caused the State of Georgia to suffer damages.

COUNT IX

VIOLATION OF THE HAWAII FALSE CLAIMS ACT Haw. Rev. Stat. § 661-21, *et seq.*

112) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

113) This count sets forth claims for treble damages and forfeitures under the Hawaii False Claims Act.

114) Through the acts described above, Defendants knowingly caused to be presented to the Hawaii Medicaid Program fraudulent claims, records, and statements.

115) Defendants knowingly violated:

- i. Haw. Rev. Stat. § 661-21(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
- ii. Haw. Rev. Stat. § 661-21(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or
- iii. Haw. Rev. Stat. § 661-21(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

116) Defendants knowingly presented false claims for payment to the State of Hawaii. The State of Hawaii, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Hawaii Medicaid Program for claims that otherwise would not have been allowed.

117) Defendants' unlawful conduct is continuing in nature and has caused the State of Hawaii to suffer damages.

COUNT X

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 Ill. Comp. Stat. § 175/3, *et seq.*

118) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

119) This count sets forth claims for treble damages and forfeitures under the Illinois Whistleblower Reward and Protection Act.

120) Through the acts described above, Defendants knowingly caused to be presented to the Illinois Medicaid Program fraudulent claims, records, and statements.

121) Defendants knowingly violated:

- i. 740 Ill. Comp. Stat. § 175/3(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. 740 Ill. Comp. Stat. § 175/3(a)(1)(B) knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. 740 Ill. Comp. Stat. § 175/3(a)(1)(G) by 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 State, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the State.

122) Defendants knowingly presented false claims for payment to the State of Illinois. The State of Illinois, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Illinois Medicaid Program for claims that otherwise would not have been allowed.

123) Defendants' unlawful conduct is continuing in nature and has caused the State of Illinois to suffer damages.

COUNT XI

**VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER
PROTECTION ACT
IC 5-11-5.5, *et seq.***

124) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

125) This count sets forth claims for treble damages and forfeitures under the Indiana False Claims and Whistleblower Protection Act.

126) Through the acts described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program fraudulent claims, records, and statements.

127) Defendants knowingly violated:

- i. IC 5-11-5.5-2(b)(1) by knowingly or intentionally presenting a false claim to the state for payment or approval;
- ii. IC 5-11-5.5-2(b)(2) by knowingly or intentionally making or using a false record or statement to obtain payment or approval of a false claim from the state; and/or
- iii. IC 5-1—5.5-2(b)(6) by knowingly or intentionally making or using a false record or statement to avoid an obligation to pay or transmit property to the state.

128) Defendants knowingly presented false claims for payment to the State of Indiana. The State of Indiana, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Indiana Medicaid Program for claims that otherwise would not have been allowed.

129) Defendants' unlawful conduct is continuing in nature and has caused the State of Indiana to suffer damages.

COUNT XII

VIOLATION OF THE IOWA FALSE CLAIMS ACT
2010 Acts, ch. 1031 § 685, *et seq.*

130) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

131) This count sets forth claims for treble damages and forfeitures under the Iowa False Claims Act.

132) Through the acts described above, Defendants knowingly caused to be presented to the Iowa Medicaid Program fraudulent claims, records, and statements.

133) Defendants knowingly violated:

- i. 2010 Acts, ch. 1031 § 685.2(1)(a) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. 2010 Acts, ch. 1031 § 685.2(1)(b) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. 2010 Acts, ch. 1031 § 685.2(1)(g) by 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 state, or knowingly conceals or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the state.

134) Defendants knowingly presented false claims for payment to the State of Iowa. The State of Iowa, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Iowa Medicaid Program for claims that otherwise would not have been allowed.

135) Defendants' unlawful conduct is continuing in nature and has caused the State of Iowa to suffer damages.

COUNT XIII

**VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY
LAW**

La. Rev. Stat. Tit. 46 § 438, *et seq.*

136) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

137) This count sets forth claims for treble damages and forfeitures under the Louisiana Medical Assistance Programs Integrity Law.

138) Through the acts described above, Defendants knowingly caused to be presented to the Louisiana Medicaid Program fraudulent claims, records, and statements.

139) Defendants knowingly violated:

- i. La. Rev. Stat. Tit. 46 § 438.3(A) by knowingly presenting or causing to be presented a false or fraudulent claim; and/or
- ii. La. Rev. Stat. Tit. 46 § 438.3(B) by knowingly engaging in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

140) Defendants knowingly presented false claims for payment to the State of Louisiana. The State of Louisiana, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Louisiana Medicaid Program for claims that otherwise would not have been allowed.

141) Defendants' unlawful conduct is continuing in nature and has caused the State of Louisiana to suffer damages.

COUNT XIV

**VIOLATION OF THE MARYLAND FALSE HEALTH CLAIMS ACT
Maryland Laws Ch. 4 (S.B. 279) 2-602 *et seq.***

142) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

143) This count sets forth claims for treble damages and forfeitures under the Maryland False Health Claims Act.

144) Through the acts described above, Defendants knowingly caused to be presented to the Maryland Medicaid Program fraudulent claims, records, and statements.

145) Defendants knowingly violated:

- i. Maryland Laws Ch. 4 (S.B. 279) 2-602(a)(1) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;
- ii. Maryland Laws Ch. 4 (S.B. 279) 2-602(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. Maryland Laws Ch. 4 (S.B. 279) 2-602(a)(7) by 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 other property to the State.

146) Defendants knowingly presented false claims for payment to the State of Maryland. The State of Maryland, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Maryland Medicaid Program for claims that otherwise would not have been allowed.

147) Defendants' unlawful conduct is continuing in nature and has caused the State of Maryland to suffer damages.

COUNT XV

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT
Mass. Gen. Laws Ch. 12 § 5B *et seq.*

148) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

149) This count sets forth claims for treble damages and forfeitures under the Massachusetts False Claims Act.

150) Through the acts described above, Defendants knowingly caused to be presented to the Massachusetts Medicaid Program fraudulent claims, records, and statements.

151) Defendants knowingly violated:

- i. Mass. Gen. Laws Ch. 12 § 5B(1) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. Mass. Gen. Laws Ch. 12 § 5B(2) by knowingly making, using, or causing to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof; and/or
- iii. Mass. Gen. Laws Ch. 12 § 5B(8) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof.

152) Defendants knowingly presented false claims for payment to the Commonwealth of Massachusetts. The Commonwealth of Massachusetts, unaware of the falsity of these claims, approved, paid and participated in payments made by the Commonwealth of Massachusetts Medicaid Program for claims that otherwise would not have been allowed.

153) Defendants' unlawful conduct is continuing in nature and has caused the Commonwealth of Massachusetts to suffer damages.

COUNT XVI

**VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT
2008 P.A. 421, 400.607 *et seq.***

154) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

155) This count sets forth claims for treble damages and forfeitures under the Michigan Medicaid False Claims Act.

156) Through the acts described above, Defendants knowingly caused to be presented to the Michigan Medicaid Program fraudulent claims, records, and statements.

157) Defendants knowingly violated:

- i. 2008 P.A. 421, 400.607 § 7(1) by making or presenting or causing to be made or presented to an employee or officer of this state a claim under the social welfare act...upon or against the state, knowing the claim to be false; and/or
- ii. 2008 P.A. 421, 400.607 § 7(3) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act.

158) Defendants knowingly presented false claims for payment to the State of Michigan. The State of Michigan, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Michigan Medicaid Program for claims that otherwise would not have been allowed.

159) Defendants' unlawful conduct is continuing in nature and has caused the State of Michigan to suffer damages.

COUNT XVII

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT Minn. Sess. Laws, S.F. No. 2082, Ch. 101 § 24 *et seq.*

160) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

161) This count sets forth claims for treble damages and forfeitures under the Minnesota False Claims Act.

162) Through the acts described above, Defendants knowingly caused to be presented to the Minnesota Medicaid Program fraudulent claims, records, and statements.

163) Defendants knowingly violated:

- i. Minn. Sess. Laws, S.F. No. 2082, Ch. 101 § 25(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;
- ii. Minn. Sess. Laws, S.F. No. 2082, Ch. 101 § 25(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision; and/or
- iii. Minn. Sess. Laws, S.F. No. 2081, Ch. 101 § 25(a)(7) by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state or a political subdivision.

164) Defendants knowingly presented false claims for payment to the State of Minnesota. The State of Minnesota, unaware of the falsity of these claims, approved, paid and

participated in payments made by the State of Minnesota Medicaid Program for claims that otherwise would not have been allowed.

165) Defendants' unlawful conduct is continuing in nature and has caused the State of Minnesota to suffer damages.

COUNT XVIII

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

Mont. Code Ann. § 17-8-403, *et seq.*

166) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

167) This count sets forth claims for treble damages and forfeitures under the Montana False Claims Act.

168) Through the acts described above, Defendants knowingly caused to be presented to the Montana Medicaid Program fraudulent claims, records, and statements.

169) Defendants knowingly violated:

- i. Mont. Code Ann. § 17-8-403(1)(a) by knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
- ii. Mont. Code Ann. § 17-8-403(1)(b) by knowingly making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity; and/or
- iii. Mont. Code Ann. § 17-8-403(1)(g) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

170) Defendants knowingly presented false claims for payment to the State of Montana. The State of Montana, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Montana Medicaid Program for claims that otherwise would not have been allowed.

171) Defendants' unlawful conduct is continuing in nature and has caused the State of Montana to suffer damages.

COUNT XIX

VIOLATION OF THE NEVADA FALSE CLAIMS ACT Nev. Rev. Stat. 357.010, *et seq.*

172) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

173) This count sets forth claims for treble damages and forfeitures under the Nevada False Claims Act.

174) Through the acts described above, Defendants knowingly caused to be presented to the Nevada Medicaid Program fraudulent claims, records, and statements.

175) Defendants knowingly violated:

- i. Nev. Rev. Stat. 357.040(1)(a) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. Nev. Rev. Stat. 357.040(1)(b) by knowingly making or using, or causing to be made or used, a false record or statement to obtain payment or approval of a false claim; and/or
- iii. Nev. Rev. Stat. 357.040(1)(g) by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an

obligation to pay or transmit money or property to the State or a political subdivision.

176) Defendants knowingly presented false claims for payment to the State of Nevada. The State of Nevada, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Nevada Medicaid Program for claims that otherwise would not have been allowed.

177) Defendants' unlawful conduct is continuing in nature and has caused the State of Nevada to suffer damages.

COUNT XX

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT N.S.J.A. § 2A:32C-1, *et seq.*

178) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

179) This count sets forth claims for treble damages and forfeitures under the New Jersey False Claims Act.

180) Through the acts described above, Defendants knowingly caused to be presented to the New Jersey Medicaid Program fraudulent claims, records, and statements.

181) Defendants knowingly violated:

- i. N.S.J.A. § 2A:32C-3(3)(a) by knowingly presenting, or causing to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
- ii. N.S.J.A. § 2A:32C-3(3)(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; and/or

- iii. N.S.J.A. § 2A:32C-3(3)(g) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

182) Defendants knowingly presented false claims for payment to the State of New Jersey. The State of New Jersey, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of New Jersey Medicaid Program for claims that otherwise would not have been allowed.

183) Defendants' unlawful conduct is continuing in nature and has caused the State of New Jersey to suffer damages.

COUNT XXI

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. Stat. Ann. § 27-14-1, *et seq.*

184) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

185) This count sets forth claims for treble damages and forfeitures under the New Mexico Medicaid False Claims Act.

186) Through the acts described above, Defendants knowingly caused to be presented to the New Mexico Medicaid Program fraudulent claims, records, and statements.

187) Defendants knowingly violated:

- i. N.M. Stat. Ann. § 27-14-4(A) by presenting, or causing to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;
- ii. N.M. Stat. Ann. § 27-14-4(C) by making, using, or causing to be made or used, a record or statement to obtain a false or fraudulent claim under the Medicaid

program paid for or approved by the state knowing such record or statement is false; and/or

- iii. N.M. Stat. Ann. § 27-14-4(E) by making, using, or causing to be made or used a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false.

188) Defendants knowingly presented false claims for payment to the State of New Mexico. The State of New Mexico, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of New Mexico Medicaid Program for claims that otherwise would not have been allowed.

189) Defendants' unlawful conduct is continuing in nature and has caused the State of New Mexico to suffer damages.

COUNT XXII

VIOLATION OF THE NEW YORK STATE FALSE CLAIMS ACT N.Y. St. Fin. Law § 187, *et seq.*

190) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

191) This count sets forth claims for treble damages and forfeitures under the New York State False Claims Act.

192) Through the acts described above, Defendants knowingly caused to be presented to the New York Medicaid Program fraudulent claims, records, and statements.

193) Defendants knowingly violated:

- i. N.Y. St. Fin. Law § 189(1)(a) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;

- ii. N.Y. St. Fin. Law § 189(1)(b) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. N.Y. St. Fin. Law § 189(1)(g) by 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 state or a local government.

194) Defendants knowingly presented false claims for payment to the State of New York. The State of New York, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of New York Medicaid Program for claims that otherwise would not have been allowed.

195) Defendants' unlawful conduct is continuing in nature and has caused the State of New York to suffer damages.

COUNT XXIII

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT N.C. Sess. Law 2010-96 § 1-605 *et seq.*

196) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

197) This count sets forth claims for treble damages and forfeitures under the North Carolina False Claims Act.

198) Through the acts described above, Defendants knowingly caused to be presented to the North Carolina Medicaid Program fraudulent claims, records, and statements.

199) Defendants knowingly violated:

- i. N.C. Sess. Law 2010-96 § 1-607(a)(1) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

- ii. N.C. Sess. Law 2010-96 § 1-607(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. N.C. Sess. Law 2010-96 § 1-607(a)(7) by 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 State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

200) Defendants knowingly presented false claims for payment to the State of North Carolina. The State of North Carolina, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of North Carolina Medicaid Program for claims that otherwise would not have been allowed.

201) Defendants' unlawful conduct is continuing in nature and has caused the State of North Carolina to suffer damages.

COUNT XXIV

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 Okl. St. § 5053, *et seq.*

202) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

203) This count sets forth claims for treble damages and forfeitures under the Oklahoma Medicaid False Claims Act.

204) Through the acts described above, Defendants knowingly caused to be presented to the Oklahoma Medicaid Program fraudulent claims, records, and statements.

205) Defendants knowingly violated:

- i. 63 Okl. St. § 5053.1(B)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the State of Oklahoma a false or fraudulent claim for payment or approval;
- ii. 63 Okl. St. § 5053.1(B)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; and/or
- iii. 63 Okl. St. § 5053.1(B)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

206) Defendants knowingly presented false claims for payment to the State of Oklahoma. The State of Oklahoma, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Oklahoma Medicaid Program for claims that otherwise would not have been allowed.

207) Defendants' unlawful conduct is continuing in nature and has caused the State of Oklahoma to suffer damages.

COUNT XXV

VIOLATION OF THE RHODE ISLAND STATE FALSE CLAIMS ACT R.I. Gen. Laws § 9-1.1-1, *et seq.*

208) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

209) This count sets forth claims for treble damages and forfeitures under the Rhode Island State False Claims Act.

210) Through the acts described above, Defendants knowingly caused to be presented to the Rhode Island Medicaid Program fraudulent claims, records, and statements.

211) Defendants knowingly violated:

- i. R.I. Gen. Laws § 9-1.1-3(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
- ii. R.I. Gen. Laws § 9-1.1-3(a)(2) by knowingly making, using, or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state; and/or
- iii. R.I. Gen. Laws § 9-1.1-3(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

212) Defendants knowingly presented false claims for payment to the State of Rhode Island. The State of Rhode Island, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Rhode Island Medicaid Program for claims that otherwise would not have been allowed.

213) Defendants' unlawful conduct is continuing in nature and has caused the State of Rhode Island to suffer damages.

COUNT XXVI

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT Tenn. Code Ann. § 71-5-181, *et seq.*

214) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

215) This count sets forth claims for treble damages and forfeitures under the Tennessee Medicaid False Claims Act.

216) Through the acts described above, Defendants knowingly caused to be presented to the Tennessee Medicaid Program fraudulent claims, records, and statements.

217) Defendants knowingly violated:

- i. Tenn. Code Ann. § 71-5-182(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval under the Medicaid program;
- ii. Tenn. Code Ann. § 71-5-182(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to get a false or fraudulent claim under the Medicaid program paid for or approved; and/or
- iii. Tenn. Code Ann. § 71-5-182(a)(1)(D) by 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 state, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state, relative to the Medicaid program.

218) Defendants knowingly presented false claims for payment to the State of Tennessee. The State of Tennessee, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Tennessee Medicaid Program for claims that otherwise would not have been allowed.

219) Defendants' unlawful conduct is continuing in nature and has caused the State of Tennessee to suffer damages.

COUNT XXVII

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION ACT
Tex. Hum. Res. Code § 36.001, *et seq.*

220) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

221) This count sets forth claims for treble damages and forfeitures under the Texas Medicaid Fraud Prevention Act.

222) Through the acts described above, Defendants knowingly caused to be presented to the Texas Medicaid Program fraudulent claims, records, and statements.

223) Defendants knowingly violated:

- i. Tex. Hum. Res. Code § 36.002(1) by knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit under the Medicaid program that is not authorized or that is greater than the benefit or payment authorized;
- ii. Tex. Hum. Res. Code § 36.002(2) by knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized; and/or
- iii. Tex. Hum. Res. Code § 36.002(12) by knowingly making, using, or causing the making or using of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

224) Defendants knowingly presented false claims for payment to the State of Texas. The State of Texas, unaware of the falsity of these claims, approved, paid and participated in

payments made by the State of Texas Medicaid Program for claims that otherwise would not have been allowed.

225) Defendants' unlawful conduct is continuing in nature and has caused the State of Texas to suffer damages.

COUNT XXVIII

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

Va. Code Ann. § 8.01-216.1, *et seq.*

226) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

227) This count sets forth claims for treble damages and forfeitures under the Virginia Fraud Against Taxpayers Act.

228) Through the acts described above, Defendants knowingly caused to be presented to the Virginia Medicaid Program fraudulent claims, records, and statements.

229) Defendants knowingly violated:

- i. Va. Code Ann. § 8.01-216.3(A)(1) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. Va. Code Ann. § 8.01-216.3(A)(2) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or
- iii. Va. Code. Ann. § 8.01-216.3(A)(7) by 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 Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth.

230) Defendants knowingly presented false claims for payment to the Commonwealth of Virginia. The Commonwealth of Virginia, unaware of the falsity of these claims, approved, paid and participated in payments made by the Commonwealth of Virginia Medicaid Program for claims that otherwise would not have been allowed.

231) Defendants' unlawful conduct is continuing in nature and has caused the Commonwealth of Virginia to suffer damages.

COUNT XXIX

VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT RCW 74.66, *et seq.*

232) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

233) This count sets forth claims for treble damages and forfeitures under the Washington State Medicaid Fraud False Claims Act.

234) Through the acts described above, Defendant knowingly caused to be presented to the Washington Medicaid Program fraudulent claims, records, and statements.

235) Defendants knowingly violated:

- i. RCW 74.66.020(1)(a) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. RCW 74.66.020(1)(b) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and
- iii. RCW 74.66.020(1)(g) by 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 a government entity, or knowingly concealing or knowingly

and improperly avoiding or decreasing an obligation to pay or transmit money or property to a government entity.

236) Defendants knowingly presented false claims for payment to the State of Washington. The State of Washington, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Washington Medicaid Program for claims that otherwise would not have been allowed.

237) Defendants' unlawful conduct is continuing in nature and has caused the State of Washington to suffer damages.

COUNT XXX

VIOLATION OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

2007 Wis. Act 20.931, *et seq.*

238) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

239) This count sets forth claims for treble damages and forfeitures under the Wisconsin False Claims for Medical Assistance Law.

240) Through the acts described above, Defendants knowingly caused to be presented to the Wisconsin Medicaid Program fraudulent claims, records, and statements.

241) Defendants knowingly violated:

- i. 2007 Wis. Act 20.931(2)(a) by knowingly presenting or causing to be presented to any officer, employee, or agent of this state a false claim for medical assistance;
- ii. 2007 Wis. Act 20.931(2)(b) by knowingly making, using, or causing to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance; and/or

- iii. 2007 Wis. Act 20.931(2)(g) by knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid or decrease any obligation to pay or transmit money or property to the Medical Assistance program.

242) Defendants knowingly presented false claims for payment to the State of Wisconsin. The State of Wisconsin, unaware of the falsity of these claims, approved, paid and participated in payments made by the State of Wisconsin Medicaid Program for claims that otherwise would not have been allowed.

243) Defendants' unlawful conduct is continuing in nature and has caused the State of Wisconsin to suffer damages.

COUNT XXXI

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. Code § 2-308.02, *et seq.*

244) Relator realleges and incorporates by reference the allegations of paragraphs 1 through 62 as though fully set forth herein.

245) This count sets forth claims for treble damages and forfeitures under the District of Columbia False Claims for Medical Assistance Law.

246) Through the acts described above, Defendants knowingly caused to be presented to the District of Columbia Medicaid Program fraudulent claims, records, and statements.

247) Defendants knowingly violated:

- i. D.C. Code § 2-308.02(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the District a false or fraudulent claim for payment or approval;

- ii. D.C. Code § 2-308.02(a)(2) by knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the District; and/or
- iii. D.C. Code § 2-308.02(a)(7) by knowingly making or using or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District.

248) Defendants knowingly presented false claims for payment to the District of Columbia. The District of Columbia, unaware of the falsity of these claims, approved, paid and participated in payments made by the District of Columbia Medicaid Program for claims that otherwise would not have been allowed.

249) Defendants' unlawful conduct is continuing in nature and has caused the District of Columbia to suffer damages.

PRAYER

WHEREFORE, Relator Heather Murray, on behalf of the United States and the Plaintiff States, requests:

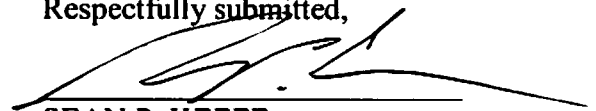
- a. This Court enter an order determining that Defendants violated the Federal and State False Claims Acts by causing healthcare professionals to bill Government Payors for the off-label and non-approved use of Thrombate III and for unlawfully retaining overpayments;
- b. Defendants pay an amount equal to three times the amount of damages the United States and the Plaintiff States have sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than \$11,000 for each violation of the Federal and State False Claims Acts;

- c. Defendants cease and desist from violating the Federal and State False Claims Acts;
- d. Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to the Federal and State False Claims Acts;
- e. The United States, the Plaintiff States and Relator be granted all such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Relator hereby demands a trial by jury.

Respectfully submitted,



SEAN P. KEEFE

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ELAINE STROMGREN

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Tampa, Florida 33609

Phone: (813) 397-2300

Fax (813)397-2310

Lead Counsel for Relator

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained hereon neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

United States of America, ex rel. Heather Murray

DEFENDANTS

Grifols Biologicals, Inc.; Grifols S.A.; and Grifols, Inc.

(b) County of Residence of First Listed Plaintiff

(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Los Angeles County, CA

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys (Firm Name, Address, and Telephone Number)

Sean P. Keefe - James Hoyer, P.A., One Urban Centre, 4830 West Kennedy Blvd., #550, Tampa, FL 33609; Telephone: 813-397-2300

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
☐ 2 U.S. Government Defendant
☐ 3 Federal Question (U.S. Government Not a Party)
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff, and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated or Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated and Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	PERSONAL INJURY ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Med. Malpractice	PERSONAL INJURY ☐ 365 Personal Injury - Product Liability ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability LABOR ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 PROPERTY RIGHTS ☐ 820 Copyrights ☐ 830 Patent ☐ 840 Trademark SOCIAL SECURITY ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☒ 375 False Claims Act ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY ☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	CIVIL RIGHTS ☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	PRISONER PETITIONS ☐ 510 Motions to Vacate Sentence Habeas Corpus: ☐ 530 General ☐ 535 Death Penalty ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement	FEDERAL TAX SUITS ☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	
		IMMIGRATION ☐ 462 Naturalization Application ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition) ☐ 465 Other Immigration Actions		

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from another district (specify)
☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

31 U.S.C. Sec. 3729-3732

Brief description of cause:
 Federal False Claims Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint.

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions)

JUDGE

DOCKET NUMBER

DATE

01/28/2016

SIGNATURE OF ATTORNEY OF RECORD

Sean P. Keefe - Bar No.: 0413828

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE