IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF ARKANSAS	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF CALIFORNIA	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF COLORADO	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF CONNECTICUT	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF DELAWARE	)
ex rel. CYNTHIA KIRK	)
	)
DISTRICT OF COLUMBIA	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF FLORIDA	)
ex rel. CYNTHIA KIRK	)
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STATE OF GEORGIA	)
ex rel. CYNTHIA KIRK	)
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STATE OF HAWAII	)
ex rel. CYNTHIA KIRK	)
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STATE OF ILLINOIS	)
ex rel. CYNTHIA KIRK	)
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STATE OF INDIANA	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF LOUISIANA	)
MEDICAL ASSISTANCE PROGRAMS	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF MARYLAND	)
ex rel. CYNTHIA KIRK	)

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STATE OF MASSACHUSETTS	)
ex rel. CYNTHIA KIRK	)
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STATE OF MICHIGAN	)
ex rel. CYNTHIA KIRK	)
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STATE OF MINNESOTA	)
ex rel. CYNTHIA KIRK	)
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STATE OF MISSOURI	)
ex rel. CYNTHIA KIRK	)
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STATE OF MONTANA	)
ex rel. CYNTHIA KIRK	)
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STATE OF NEVADA	)
ex rel. CYNTHIA KIRK	)
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STATE OF NEW HAMPSHIRE	)
ex rel. CYNTHIA KIRK	)
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STATE OF NEW JERSEY	)
ex rel. CYNTHIA KIRK	)
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STATE OF NEW MEXICO	)
ex rel. CYNTHIA KIRK	)
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STATE OF NEW YORK	)
ex rel. CYNTHIA KIRK	)
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STATE OF NORTH CAROLINA	)
ex rel. CYNTHIA KIRK	)
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STATE OF OKLAHOMA	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF RHODE ISLAND	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF TENNESSEE	)
ex rel. CYNTHIA KIRK	)
	)
STATE OF TEXAS	)
ex rel. CYNTHIA KIRK	)
	)

STATE OF UTAH ex rel. CYNTHIA KIRK	)	
STATE OF VIRGINIA ex rel. CYNTHIA KIRK,	)	
STATE OF WISCONSIN ex rel. CYNTHIA KIRK	)	
Plaintiffs,	)	
	)	Case No. 2:10-cv-02492-SAC-KGS
v.	)	
CAREFUSION CORPORATION Registered Agent: Corporation Service Co. 200 SW 30th Street Topeka, KS 66611	)	**FILED UNDER SEAL** **PURSUANT TO** **31 U.S.C. § 3730** **DO NOT PLACE IN PRESS BOX**
and	)	
CARDINAL HEALTH, INC. Registered Agent: Corporation Service Co. 200 SW 30th Street Topeka, KS 66611	)	
Defendants.	)	**DO NOT ENTER ON PACER**

SECOND AMENDED COMPLAINT

Plaintiff United States of America ("USA"), ex rel. Cynthia Kirk ("Relator"), and the State of Arkansas, State of California, State of Colorado, State of Connecticut, State of Delaware, District of Columbia, State of Florida, State of Georgia, State of Hawaii, State of Illinois, State of Indiana, State of Louisiana Medical Assistance Programs, State of Maryland, State of Massachusetts, State of Michigan, State of Minnesota, State of Missouri, State of Montana, State of Nevada, State of New Hampshire, 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, State of Utah, State of Virginia and State of Wisconsin for their Second Amended Complaint against defendants CareFusion Corporation and Cardinal Health, Inc., Inc. for treble damages and civil penalties arising from defendants' off-label marketing practices and kickbacks that induced false claims to be made to Medicare and Medicaid and other government entities in violation of 31 U.S.C. § 3729 *et seq.*, and corresponding state false claims and whistleblower reward and protection statutes as alleged herein, allege and state as follows:

JURISDICTION, VENUE AND STATUTORY REQUIREMENTS

1. This action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and corresponding claims under state statutes. Jurisdiction in this Court is proper pursuant to 31 U.S.C. §§ 3732(a), (b) and 3730(b) and 28 U.S.C. § 1331.

2. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 because the acts proscribed by 31 U.S.C. §§ 3729 *et seq.* and corresponding state statutes and complained of herein took place in part in this district and Defendants transacted business in this district.

3. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator has served with her Second Amended Complaint to the Attorney General of the United States and the United States Attorney for the District of Kansas a statement of all material evidence and information currently in her possession and of which she is the original source. This disclosure statement is supported by material evidence known to Relator at the time of filing establishing the existence of Defendants' false claims. Because the statement includes attorney-client communications and work product of Realtor's attorneys, and

was submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential. Relator will also comply with the service requirements of all state false claim and whistleblower reward and protection acts to the fullest extent possible pursuant to 31 USC § 3731(3)(c) (as amended by the Fraud Enforcement and Recovery Act of 2009, 123 Stat 1617 (May 20, 2009)).

PARTIES

4. Relator Cynthia Kirk, PhD RAC, is an individual residing at 19012 West 98th Terrace, Lenexa, KS 66220.

5. Relator is the original source of the facts and information set forth in this Second Amended Complaint concerning the activities of Defendants. The facts alleged herein are based entirely on her direct, independent knowledge, personal observations and documents in her possession and also on information and belief.

6. From September 17, 2009, until the date of this filing, Relator Kirk has been Vice President of Regulatory Affairs for the Infection Prevention Business Unit of Defendant CareFusion Corporation ("CareFusion"). Shortly after bringing the compliance violations outlined in this Second Amended Complaint to the attention of senior management at Defendant CareFusion, CareFusion terminated Relator.

7. Defendant CareFusion is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 3750 Torrey View Court, San Diego, CA 92130. It also has an office at 11400 Tomahawk Creek Parkway, Ste. 310, Leawood, KS 66211.

8. CareFusion is a publicly traded company principally engaged in the development, out-source manufacturing, marketing and sale of pharmaceutical drugs and devices, including over-the-counter drugs falling under the jurisdiction and regulation of the United States Food and Drug Administration ("FDA"). In 2009, CareFusion had pro forma revenues of $3.7 billion.

9. CareFusion sells ChloraPrep products, which are a line of drug products regulated by the FDA. ChloraPrep products are at the heart of this Second Amended Complaint.

10. The history of the ChloraPrep products starts in 2000 when a company called Medi-Flex, Inc. started manufacturing and selling ChloraPrep products. Medi-Flex changed its name to Enturia, Inc. in January 2007. In May 2008, Enturia was sold to Defendant Cardinal Health, Inc. ("Cardinal Health").

11. Defendant Cardinal Health is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.

12. Cardinal Health is a publicly traded $96 billion health care services company that also is engaged in the development, out-source manufacturing, marketing and sale of pharmaceutical drugs and devices, including over the counter drugs falling under the jurisdiction and regulation of the FDA.

13. In 2009, Defendant Cardinal Health spun off its Division that sold ChloraPrep products to form Defendant CareFusion.

FACTUAL BACKGROUND

14. The ChloraPrep products are over-the-counter products regulated by the FDA as drugs.

15. The Defendants must have FDA approval to market and sell ChloraPrep products.

16. ChloraPrep products are a collection of antiseptic products provided in clear, teal and orange colored solution applied through various sized applicators to surgery patients' skin before an incision or injection is made. Only licensed health care professionals can administer ChloraPrep products on patients.

17. ChloraPrep is the #1 selling drug in its class. It has very few name-brand competitors and currently no generic competitors. It is also the most expensive drug in its class. Less expensive alternative skin pre-operative antiseptics include povidone iodine, iodine povacrylix, and sponges soaked in solutions such as exidine, which is 2% chlorhexidine gluconate.

18. ChloraPrep is and has been highly profitable for Defendants. Projected revenue for ChloraPrep in 2010 is $193 million.

19. The FDA approved ChloraPrep in July 2000 only for the preparation of the patient's skin prior to surgery or injection.

20. It was not until July 2010 that the FDA approved the addition of the following to the original indication: "to help reduce bacteria that potentially can cause skin infection."

21. The FDA has never approved ChloraPrep products to be used for the "prevention of infection" or "reduction of infection" or prevention or reduction of microorganisms.

22. In fact, the FDA has stated that the reduction of *bacteria* is not the same as the prevention or reduction of *infection*. Specifically, the FDA has stated that "there are no corresponding clinical data that demonstrate the bacterial reductions of the required magnitude to produce a reduction in clinical infection rates." The FDA has also stated that a "top priority" of the FDA is enforcement of off-label antiseptic claims about microorganisms.

23. In spite of this, beginning in at least 2002 and continuing to the present, Defendants have been illegally marketing and selling ChloraPrep products to hospitals, surgery centers, doctors and nurses for the "prevention of infection" and/or "reduction of infection," and/or "reduction of microorganisms," all without FDA approval. In addition, from at least 2002 and continuing to the present, Defendants have been illegally marketing and selling ChloraPrep products to their customers for other (more specific) off-label and illegal uses such as the prevention and reduction of surgical site infections, the prevention and reduction of catheter-related bloodstream infections, the prevention and reduction of bloodstream infections, and effectiveness in blood and organic matter.

24. In addition, from at least 2002 through July 2010, Defendants illegally marketed and sold ChloraPrep products to hospitals, doctors and nurses for the "reduction of bacteria that potentially cause skin infection," all without FDA approval during that timeframe.

25. Defendants made these illegal and off-label marketing claims to induce their customers to pay the premium price for ChloraPrep. As outlined in detail below, Defendants promoted ChloraPrep as preventing and reducing infections and induced customers to pay for the more expensive ChloraPrep products with the belief that it would save them money in the long run by preventing and reducing infections. As stated to Relator on October 8, 2009, by Senior Vice President Mike Kelly, "Preventing infection impacts my bottom line."

26. In addition, from 2006 through 2008 Enturia/Defendant Cardinal Health illegally marketed and sold ChloraPrep Hi-Lite Orange (a best-selling ChloraPrep product line) to hospitals, doctors and nurses without any FDA approval of Hi-Lite Orange. The FDA did not approve Hi-Lite Orange to be sold or marketed at all until July 2008.

27. Similarly, from May 2005 to June 2009 Enturia/Defendant Cardinal Health illegally marketed and sold ChloraPrep Triple Swabsticks to hospitals, doctors and nurses without any FDA approval of Triple Swab. The FDA did not approve Triple Swabsticks to be sold or marketed at all until June 2009.

28. Because the FDA has not approved ChloraPrep for the reduction or prevention of infection or microorganisms or any of the other more specific off-label claims set forth in paragraph 23, and the FDA had not approved ChloraPrep for the reduction of bacteria until July 2010, the FDA had not approved Hi-Lite Orange as a drug that was safe and effective to sell until June 2008, and the FDA had not approved ChloraPrep Triple Swabstick as a drug that was safe and effective to sell until June 2009,

Defendants have been marketing ChloraPrep products in an illegal off-label manner for almost a decade and continuing to the present.

29. Under applicable statutes and regulations, the seller or manufacturer of a drug regulated by the FDA may not promote or market the use of the drug for purposes or in a manner other than those approved by the FDA.

30. The use of a drug for a purpose other than those approved by the FDA is referred to as "off-label" use.

31. The promotion by a drug company of "off-label" uses of FDA-regulated drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government and the FDA.

32. After the launch of ChloraPrep products in 2000, Defendants formed a scheme to increase sales of ChloraPrep products by marketing them for the "prevention of infection" and "reduction of infection" while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of ChloraPrep products.

33. In fact, ChloraPrep products are sold by a CareFusion business unit called the "Infection Prevention Business Unit."

34. The ChloraPrep Infection Prevention Business Unit was previously headed by Mike Kelly, Senior Vice President. It is currently headed by Jason Strohm.

35. Kelly also headed the ChloraPrep product line when he was employed by Defendant Cardinal Health before Cardinal Health spun-off to create CareFusion. Kelly moved from Cardinal Health to CareFusion as part of the spin-off in 2009. Kelly was part of the Cardinal Health due diligence team that reviewed Enturia's ChloraPrep files

and FDA correspondence in connection with Cardinal Health's acquisition of ChloraPrep in May 2008.

36. The President of the CareFusion Division (referred to internally as "MTS" or the Medical and Technical Services Division) is Vivek Jain. Jain reports to Dave Schlotterbeck, the Chief Executive Officer of CareFusion.

37. Karen Weaver and Carlos Fonseca are In-House General Counsel of CareFusion.

38. During her tenure with CareFusion, Relator reported directly to Tom Rasnic, Vice President of Regulatory Affairs and Quality. Relator reported indirectly to Mike Kelly.

39. Mike Baltezor was the previous Vice President of Research and Development and Regulatory Affairs.

40. Cindi Crosby is the Vice President of Medical Affairs.

41. Jan Creidenberg is the Vice President of Sales and Marketing.

42. Shortly after Relator expressed concerns to CareFusion executives including but not limited to Vivek Jain and Mike Kelly that Care Fusion was engaging in illegal activities, CareFusion terminated Relator.

43. CareFusion does not have any Compliance Committee in place and eliminated Relator's position (Vice President of Regulatory Affairs) from the company.

DEFENDANTS HAVE RECEIVED AND CONTINUE TO RECEIVE MILLIONS OF DOLLARS FROM GOVERNMENT-FUNDED HEALTH CARE PLANS LIKE MEDICARE AND MEDICAID AND GOVERNMENT HEALTHCARE FACILITIES FOR CHLORAPREP PRODUCTS THEY PROMOTE WITH ILLEGAL OFF-LABEL TACTICS

44. More than 100 million people – 1 in 3 – now have government-sponsored health care coverage through Medicaid, Medicare, military and federal and state employee health care plans (collectively referred to here as "Government-Funded Plans").

45. It is lucrative for drug companies like Defendants to have their drug approved by Government-Funded Plans because so many Americans are covered by Government-Funded Plans. In addition, unlike private insurance plans, the drugs covered by Government-Funded Plans are not frequently reviewed to determine whether the coverage status should change. Once a drug is approved as a drug covered by a Government-Funded Plan, it generally remains a covered drug regardless of whether the product formulation is later changed and regardless of whether unapproved uses are later claimed after initial approval. Thus, the Government-Funded Plans were and continue to be attractive targets for Defendants because they would be paid year after year for ChloraPrep with no questions asked.

46. Defendants seized the opportunity to increase their ChloraPrep product sales to the millions of patients covered by Government-Funded Plans and to government healthcare facilities by orchestrating a scheme to aggressively market ChloraPrep products to hospitals, doctors and nurses for the off-label use of preventing and reducing infection.

47. The scheme consisted of an elaborate and blatant promotion of off-label use of ChloraPrep products for the prevention of infection, all in direct contravention of the rules and regulations of the FDA.

48. Relator advised CareFusion executives that CareFusion's marketing and promotion of ChloraPrep products was off-label.

49. Nevertheless, CareFusion continued its off-label marketing practices.

SPECIFIC ACTS IN FURTHERANCE OF THE SCHEME BY DEFENDANTS TO KNOWINGLY CAUSE FALSE CLAIMS TO BE PRESENTED TO GOVERNMENT-FUNDED PLANS

Defendants' Active Solicitation, Marketing and Promotion of Unapproved Drugs

50. Only one ChloraPrep surgical product was approved by the FDA in 2000 – it was a 3 ml applicator containing a clear ChloraPrep solution. After that, if the color, dose application or applicator changed, it required new FDA approval, as the safety and/or efficacy could be altered by these changes in the product.

51. In October 2006, Enturia (which, as outlined above, was sold to Defendant Cardinal Health in May 2008) introduced a new ChloraPrep product into the market – ChloraPrep Hi-Lite Orange products in 3 different sized applicators – and sought the required FDA approval.

52. The Federal Food, Drug, and Cosmetic Act ("FDCA"), among other things, governs the interstate distribution of drugs for human use, as codified in 21 U.S.C. § 301. The FDCA and its implementing regulations prohibit the distribution of any new drug like ChloraPrep Hi-Lite Orange into interstate commerce until the sponsor or manufacturer of that new drug has received approval from the FDA, based on an intensive application and review process. *See* 21 U.S.C. § 355.

53. Although Enturia/Cardinal Health submitted an application for the approval of Hi-Lite Orange in 2006, the FDA determined that it could not and would not approve Hi-Lite Orange at that time because the application contained deficient information. There was no FDA approval *at all* for the Hi-Lite Orange products until June 2008.

54. Nevertheless, for two years from August 18, 2006, through June 2008, Enturia/Defendant Cardinal Health promoted and sold Hi-Lite Orange ChloraPrep products that had no FDA approval at all.

55. During the time that there was no FDA approval for ChloraPrep Hi-Lite Orange, Enturia/Defendant Cardinal Health supplied their customers with a Patient Sheet to hand out to patients who had Hi-Lite Orange applied to their skin during surgery. The Patient Sheet is entitled, "Why is my skin orange after surgery?" and contains pictures of "various skin tones showing ChloraPrep Hi-Lite Orange Tint."

56. The Patient Sheet also claims, "About the orange tint: The FDA considers the dye safe for use, and it is used in a variety of ways for health care purposes." Enturia/Defendant Cardinal Health made this statement at a time when it knew that the FDA had not approved the orange tint in ChloraPrep as being safe and effective, and indeed, at the time that Enturia/Cardinal Health made this claim, the FDA had requested additional information that it needed to make a determination of safety and efficacy.

57. A press release dated February 8, 2007, announcing the exclusive arrangement between Enturia/Defendant Cardinal Health and Arrow to distribute Hi-Lite Orange at the time states, "Hi-Lite Orange tinted ChloraPrep highlights the prepped area, adding an extra level of **infection risk-reduction** confidence to the central venous

catheter insertion process." (Emphasis added.) According to the President of Enturia at the time, "We are very pleased about this agreement with Arrow, as it fits well within Enturia's vision of helping **fight healthcare-associated infection**. This will help ensure that hospitals have access to leading products that have proven success in **reducing the risk of catheter-related bloodstream infections**." (Emphasis added.)

58. Both before and after the FDA approved Hi-Lite Orange ChloraPrep as being safe and effective to market and sell, Enturia/Defendant Cardinal Health/Defendant CareFusion have marketed and are marketing Orange Hi-Lite ChloraPrep products for the "reduction of infection" and "prevention of infection" – claims that, to this day, have not been approved by the FDA.

59. For example, CareFusion marketing materials that the CareFusion sales force uses to sell Hi-Lite Orange to the Infection Prevention Units in hospitals state, "Part of a complete line of site preparation products to help **stop infection** at the source." (Emphasis added.)

60. CareFusion knew that it did not have the required FDA approval for Hi-Lite Orange.

61. Nevertheless, CareFusion continued its illegal and off-label marketing practices of Hi-Lite Orange ChloraPrep products to increase its revenues.

62. Hi-Lite Orange is the top selling line of ChloraPrep products.

63. The marketing of Hi-Lite Orange without any FDA approval followed by the off-label marketing of Hi-Lite Orange for the prevention and reduction of infection was extremely profitable for Defendants. Revenue from the Hi-Lite Orange line alone went from $80 million in 2005 to $140 million in 2007.

64. In May 2005, Enturia (which, as outlined above, was sold to Defendant Cardinal Health in May 2008) introduced another new ChloraPrep product into the market – ChloraPrep Triple Swabstick (referred to here as "Triple Swab")– and sought the required FDA approval.

65. Although Enturia/Cardinal Health submitted an application for the approval of Triple Swab in May 2005, the FDA determined that it could not and would not approve Triple Swab at that time because the application contained deficient information. There was no FDA approval *at all* for Triple Swab until June 10, 2009.

66. Nevertheless, for four years from at least May 10, 2005, through June 10, 2009, Enturia/Defendant Cardinal Health promoted and sold Triple Swab with no FDA approval at all.

67. During the time that there was no FDA approval for Triple Swab, Enturia/Defendant Cardinal Health executive Cindy Crosby (then Vice President of Clinical Affairs who still holds no Medical Degree) made the promotional statements about the Triple Swab (as well as the ChloraPrep Single Swabstick (referred to here as "Single Swab")): "The ChloraPrep(R) Swabstick is clearly a **superior product** combining advanced design technology with the best antiseptic available for **infection prevention**." (Emphasis added.)

68. In June 2005, Crosby also made the following promotional statements about Triple Swab and Single Swab: "Clinical studies **comparing chlorhexidine to povidone iodine** consistently demonstrate **reduction rates of 50% for catheter-related bloodstream infections**. Furthermore in clinical practice ChloraPrep(R) has consistently

demonstrated **a reduction in healthcare associated infections when replacing alcohol and iodine**." (Emphasis added.)

69. Furthermore, Crosby was untruthful about FDA approval for Triple Swab. Referring to both the Single Swab and Triple Swab, she stated, "the Center for Disease Control ("CDC") Guidelines for the Prevention of Intravascular Catheter-Related Infections Infection state that for cutaneous antisepsis, 'a 2% chlorhexidine-based preparation is preferred.' **ChloraPrep® is the only 2% chlorhexidine gluconate/70% isopropyl alcohol patient preoperative skin prep approved by the FDA that meets CDC's guidelines**." (Emphasis added.)

70. In 2005 Defendants (then called "Enturia") advertised the "Product Benefits" of Triple Swab on their website as:

- **Rapid-acting: Rapidly kills a broad spectrum of skin-dwelling microorganisms.**
- **Broad spectrum: Effective against gram-positive and gram-negative bacteria including Methicillin-resistant Staphlycoccus aureus (MRSA), Vancomycin-resistant Enterococci (VRE), difficile, Acineobacter, and most viruses and fungi.**
- **Active in protein-rich biomaterials: Remains active in the presence of blood, serum, and protein-rich biomaterials.**

(Emphasis added.)

71. Meanwhile, during the time that Enturia/Cardinal Health was making these claims, the FDA had requested additional information (a clinical study) that it needed to make a determination of safety and efficacy.

72. Enturia/Defendant Cardinal Health made these statements at a time when it knew that the FDA had not approved the Triple Swab as even being safe and effective, let alone capable of preventing or reducing infection or being effective against MRSA, VRE, microorganisms or remaining active in biomaterials. To this day the FDA has never approved these claims.

73. And yet, as of the date this Second Amended Petition was filed, Defendants are illegally marketing and selling the Single Swab and Triple Swab as being "[p]art of a **complete line of skin preparation products to help reduce the risk of infection** at the source." (Emphasis added.)

Defendants' Active Solicitation, Marketing and Promotion of Off-Label Uses of Other ChloraPrep Products:

74. Hi-Lite Orange and Triple Swab were not the only ChloraPrep product lines that Defendants illegally marketed.

75. In 2002, the FDA approved another ChloraPrep product (clear in color) in a smaller applicator called a "Frepp." In 2003, the FDA approved another ChloraPrep product (also clear in color) in a 10.5 ml applicator. In 2004, the FDA approved a 26 ml clear ChloraPrep product. In 2005, the FDA approved a 26 ml teal-colored ChloraPrep product. In 2006, the FDA approved a 10.5 ml teal-colored ChloraPrep product. With these five FDA approvals (as with the initial FDA approval in 2000 and the Hi-Lite Orange approval in June 2008), the approved indicated use was only for the preparation of the patient's skin prior to surgery or injection.

76. Despite this limited approved use, starting in or around 2002, Medi-Flex/Enturia (which, as outlined above, was sold to Defendant Cardinal Health in 2008, which spun off the ChloraPrep Division to form CareFusion in 2009) started making off-

label marketing claims that ChloraPrep products should be used for the "prevention of infection" and "reduction of infection."

77. The two main ingredients in ChloraPrep are 2% chlorhexidine gluconate and 70% isopropyl alcohol. In 2002, Medi-Flex/Enturia/Defendant Cardinal Health issued a press release stating, in part, "In fact, the combination of chlorhexidine and alcohol in ChloraPrep produces better immediate, residual, and cumulative bactericidal activity than alcohol and iodophor solutions. Furthermore, ChloraPrep is persistent in **killing a broad spectrum of microorganisms** on the skin for at least 48 hours versus two to three hours for iodophors. Unlike iodophors, **ChloraPrep remains active in the presence of blood or organic matter**…Clinical studies comparing chlorhexidine to povidone iodine consistently demonstrate **reduction rates of 50% for catheter-related bloodstream infections**. As a recommended skin prep for catheter insertion, **ChloraPrep has been the deciding factor in the success of several hospitals' infection reduction** programs.") (Emphasis added.)

78. In 2005, the President of the ChloraPrep product line at the time, James Mitchum, told the Kansas City Business Journal, "Here I have the opportunity [of] **preventing the infection** in the first place." (Emphasis added.)

79. In addition to the general claims of infection prevention and infection reduction, Defendants Cardinal Health and CareFusion made off-label claims and marketed ChloraPrep products for "surgical site infection prevention," "catheter-related bloodstream infection prevention," preventing or reducing microorganisms, preventing or reducing bloodstream infections, and a lasting presence in blood or organic matter.

80. In 2005, Medi-Flex/Enturia/Defendant Cardinal Health issued a press release stating, "Clinical studies comparing Chlorhexidine to povidone iodine consistently demonstrate **reduction rates of 50% for catheter-related bloodstream infections."** (Emphasis added.), and, "Furthermore, ChloraPrep is persistent in **killing a broad spectrum of microorganisms** on the skin for at least 48 hours…ChloraPrep **remains active in the presence of blood or organic matter**." The off-label claim that "ChloraPrep remains active in the presence of blood or organic matter" is also false and misleading because CareFusion has a study that ChloraPrep is *inactive* in blood or organic matter.

81. In 2005, Medi-Flex/Enturia/Defendant Cardinal Health issued a newsletter (Volume 3, Issue 7) containing the statements, "**The surgery is over. Your patient is in recovery. Is the antiseptic skin prep you used still fighting surgical site infection? It is if you used ChloraPrep: ChloraPrep is more effective than iodine-based products at reducing the bacteria on the skin that can cause an infection. The chlorhexidine in ChloraPrep prevents regrowth of microorganisms on the skin for at least 48 hours…In your battle against surgical site infection, fewer microorganisms on the skin can mean a reduced risk of infection.**" (Emphasis added.)

82. In October 2007, Enturia/Defendant Cardinal Health issued a promotional piece that was printed in the "International Infection Prevention Week" flyer. It stated, "Preventative measures can reduce **the risk of infection and ChloraPrep as part of an integrated prevention platform** . . . has demonstrated a **50% reduction in the incidence of catheter-related bloodstream infections when compared to povidone iodine**." (Emphasis added.) The ChloraPrep.com website currently claims that

ChloraPrep reduces skin microorganisms that can cause bloodstream infections (BSIs) and surgical site infections (SSIs). The website also claims that ChloraPrep "**rapidly kills microorganisms**" and "**reduc[es] skin microorganisms**…"

83. Throughout the 2000s, Defendants trained their sales forces to solicit, market and promote off-label and unapproved product use of ChloraPrep products to hospitals, surgery centers, doctors and nurses for infection prevention and infection reduction.

84. Specifically, Cardinal Health and CareFusion sales representatives used marketing and promotional materials with hospitals, surgery centers, doctors and nurses that stated, "**Superior Infection Prevention starts with ChloraPrep**" (bold emphasis in original) and "ChloraPrep … a complete line of products to help stop infection."

85. In August 2009 CareFusion trained it sales representatives to, "Ensure that [ChloraPrep customers] are pleased with the performance and **SSI reduction results** since committing to ChloraPrep in the OR." (Emphasis added.)

86. Defendants made off-label claims in company press releases and on company websites. Company press releases and websites constitute labeling as defined in 21 U.S.C. § 321(m) of the FDCA and Title 21, CFR Part 202, and are considered promotional. Press release or website representations and suggestions that are false and misleading within the meaning of 21 U.S.C. § 352(a) are also considered violative advertising.

87. In May 2008, Defendant Cardinal Health issued a press release stating: "**ChloraPrep Products Expand Infection Prevention Business**" (bold emphasis in original); and "Cardinal Health, a global provider of products and services that improve

the safety and productivity of health care, today announced it has completed the acquisition of assets of privately held Enturia, Inc., **the manufacturer of infection-prevention products sold under the ChloraPrep brand name**" (emphasis added); and "**ChloraPrep brand products are used widely in the U.S. hospitals and surgery centers** as a patient preoperative skin preparation **to help prevent blood stream and surgical site infections**, two of the most common types of health care associated infections (HAIs) among surgery patients" (emphasis added); and "The ChloraPrep product line expands the company's offerings that help providers **lower infection rates**." (emphasis added).

88. In November 2009, Defendant CareFusion issued a press release stating in a section entitled "About CareFusion Corporation," "CareFusion is a global corporation serving the health care industry with products and services that help hospitals measurably improve the safety and quality of care…**ChloraPrep(R) for infection prevention**[.]" (Emphasis added.)

89. Defendant CareFusion maintains two websites that contain off-label claims about CloraPrep: www.carefusion.com and www.chloraprep.com. On September 2, 2010, CareFusion made the following off-label claims on these websites:

a. "Together, our formulation and applicator provide a proven system that supports infection control guidelines to help you **reduce the incidence of BSIs [bloodstream infections] and SSIs [surgical site infections] at your facility**." (Emphasis added.) (www.carefusion.com)

b. "Proven in 36 published outcome studies as best practice for helping **reduce the risk of infection."** (Emphasis added.) (www.carefusion.com)

c. "This helps **reduce skin microorganisms that can cause bloodstream infections (BSIs) and surgical site infections (SSIs)."** (Emphasis added.) (www.chloraprep.com)

d. "ChloraPrep applicators help improve patient outcomes by **reducing skin microorganisms that can cause bloodstream infections (BSIs) and surgical site infections (SSIs)."** (Emphasis added.) (www.chloraprep.com)

e. "When used with other CDC-recommended interventions, **ChloraPrep reduced catheter-related BSIs by 89.3%** in a Brookdale University Medical Center Clinical Study." (Emphasis added.) (www.chloraprep.com)

f. "**SSI prevention" "CRBSI prevention**: Prevention of infections related to central venous catheters and arterial catheters in intensive care patients" (Bold and underlined emphasis in original.) (www.chloraprep.com)

90. Upon information and belief, Cardinal Health and CareFusion sales representatives made off-label statements about ChloraPrep to health care professionals verbally during in-person sales calls, through marketing materials brought to the sales calls and left with the health care professionals and through the use of e-mail, all as they were trained to do by Defendants.

91. One CareFusion promotional piece instructed all of the CareFusion Infection Prevention Business Unit Sales Representatives to tell doctors and nurses in the hospital Infection Prevention Units and surgery centers that ChloraPrep products were proven to "reduce infections by 41%." The promotional piece also instructs the sales team to make the claim to customers that ChloraPrep provides a 41% reduction of infection dollar savings to the customer. Defendants used this off-label claim, and the other off-label claims outlined herein, to induce customers to pay more for ChloraPrep because of the infection cost savings that ChloraPrep allegedly provided. Upon information and belief, the sales representatives did as they were told and used the off-label promotional claims to sell ChloraPrep and justify its price, which was higher than alternative pre-operative skin preparation products.

92. Defendant CareFusion's claim that ChloraPrep could provide a cost benefit of 41% was significant to the hospitals and surgery centers. Government-Funded Health Plans do not reimburse for procedures to treat infections that occur as a result of the initial surgery. A reduction of those infections (and, correspondingly, a reduction in expenses to the hospitals for procedures that are not covered by health insurance) by 41% would be a significant savings to the hospitals and surgery centers. Defendants used this and their other off-label claims to induce customers to pay for ChloraPrep, which is more expensive than alternative pre-operative skin preparation products.

93. Defendants have also used marketing materials to promote the off-label claim that ChloraPrep reduces microorganisms. This claim is off-label because the FDA has never approved any ChloraPrep product for the reduction of microorganisms. Moreover, the statement is misleading in that when used in the context of a specific

microorganism (such as *Methicillin-resistant Staphylococcus Awreus* "MRSA" and *Vancomycin-resistent Enterococci* "VRE") it implies that ChloraPrep can prevent the underlying disease associated with the microorganisms.

94. For example, in 2005, Medi-Flex/Enturia/Defendant Cardinal Health issued a press release stating, "Furthermore, ChloraPrep is persistent in **killing a broad spectrum of microorganisms** on the skin for at least 48 hours…" (emphasis added). That 2005 press release also made the off-label claim that ChloraPrep produced "bactericidal activity," when ChloraPrep was not approved by the FDA as reducing bacteria until July 2008.

95. In a September 2006 press release, Medi-Flex/Enturia/Defendant Cardinal Health stated, "ChloraPrep, full line of patient preoperative skin preparations used to help **reduce bacteria** that can cause bloodstream and surgical site infections.…Infections contracted in hospitals are the fourth leading cause of death in the United States, causing more deaths than homicides and auto accidents combined." Again, this off-label claim was in 2006, well before the FDA approved using ChloraPrep to reduce bacteria.

96. In 2008, CareFusion's marketing materials stated, "Broad Spectrum: ChloraPrep antimicrobial activity is effective against microorganisms including gram-positive and gram-negative bacteria***, Methicillin-resistant Staphylococcus Awreus (MRSA), Vancomycin-resistant Enterococci (VRE), Clostriguim, Acineobacterm*****, and most viruses and fungi.**" (Emphasis in original.).

97. In 2008, CareFusion's marketing materials stated, "ChloraPrep has demonstrated **greater efficacy than traditional iodophors** in reducing skin microorganisms that can cause infection. **The ChloraPrep advantage** *Effective against

a broad spectrum of microorganisms, including **MRSA, C. Diff and VRE**" and "**Effective in the presence of blood and organic matter.**" (Bold emphasis in original.)

98. A May 12, 2008 Cardinal Health press release claims about CloraPrep, "The products use proprietary disposable applicators…to help **reduce skin-dwelling microorganisms that cause infections**." (Emphasis added.)

99. As of September 2, 2010, the chloraprep.com website claimed, "ChloraPrep applicators help improve patient outcomes by **reducing skin microorganisms that can cause bloodstream infections (BSIs) and surgical site infections (SSIs).**…ChloraPrep provides two distinct mechanisms of action: …rapidly **kills microorganisms** by denaturing cell proteins ….maintains persistent antimicrobial activity…" (Emphasis added.)

100. Not only are the above statements about ChloraPrep in paragraphs 23 through 99 off-label, as outlined below, the statements are also false and misleading as there is no valid scientific study proving that ChloraPrep prevents infection.

Defendant CareFusion's Illegal and Off-Label ChloraPrep Study

101. Prior to 2009, there were no published studies of ChloraPrep that demonstrated the product's safety or effectiveness in reducing or preventing infection. In 2009, CareFusion sponsored an investigational study that purported to examine the safety and efficacy of ChloraPrep teal-tinted product for the off-label uses of prevention of infection and reduction of infection. CareFusion paid millions of dollars for the study. Two authors of the study were Cindi Crosby, CareFusion's Vice President of Medical Affairs, and Rabih Darouiche of the Michael DeBakey VA Hospital in Houston. This study sponsored by CareFusion is referred to in this Second Amended Complaint as the

"ChloraPrep Study." In internal CareFusion documents and in some of its marketing materials, the ChloraPrep Study is referred to as the Surgical Site Infection Study, the "SSI Study" or the "Darouiche Study."

102. Defendant CareFusion's Vice President of Medical Affairs Cindi Crosby is not a medical doctor. She has no doctoral degree, no previous clinical experience and no qualifications for her role in this position. In addition to medical affairs, Crosby also performs sales functions for CareFusion.

103. Defendant CareFusion initially filed an amendment to its Investigational New Drug Application (or "IND") to the FDA that listed CareFusion as the sponsor of record for the ChloraPrep Study. Crosby was listed as the person responsible for monitoring the conduct and progress of the clinical investigations and the person responsible for review and evaluation of information relevant to the safety of the drug.

104. CareFusion (via Crosby) analyzed the data and authored and edited the results of the ChloraPrep Study.

105. The ChloraPrep Study sponsored by CareFusion and paid for by CareFusion concludes that ChloraPrep prevented infections by 41%. As set forth above in paragraphs 91 and 92, and as set forth in more detail below, Defendant CareFusion uses this 41 percentage figure in its promotional materials to promote the projected costs savings (in the hundreds of thousands to millions) for hospitals and used it as a way to induce customers to pay for the more expensive ChloraPrep rather than using less expensive alternatives.

106. A sponsor of a clinical study of a "new" or unapproved drug has specific obligations under the law. The study sponsor must follow rigid documentation requirements. If the sponsor fails to do so, the study is invalid.

107. The ChloraPrep Study is invalid and off-label. As outlined below in paragraph 108 subparts (a)-(n) – paragraph 111, the Study was conducted in violation of § 505 FDCA, as amended, 21 CFR § 312.

108. The ChloraPrep Study is invalid and off-label because Defendant CareFusion failed to meet statutory obligations of a sponsor in all respects in the conduct of the study by:

(a) Failing to ensure proper monitoring of the study;

(b) Failing to obtain the required number of investigator signatures the Statement of Investigators (FDA Form 1572);

(c) Failing to properly designate transfer of obligations to a Contract Research Organization (CRO) and failing to obtain a reciprocating agreement from a CRO for assuming responsibilities;

(d) Failing to supply an Investigator Brochure;

(e) Failing to review, evaluate and report safety information (7 study subjects died during the study and CareFusion failed to promptly report those deaths to the FDA);

(f) Failing to submit adequate data regarding the study as required for annual reports;

(g) Failing to submit any annual report in 2006;

(h) Failing to maintain adequate records showing receipt, shipment or other disposition of investigational drug (as a result, it is not known which ChloraPrep applicators were used in the study);

(i) Failing to obtain appropriate informed consent from patients (as a result, it is not known whether the patients were aware that they were being treated with investigational drug product);

(j) Failing to obtain appropriate Internal Review Board approval (as a result, it is not known whether the VA hospitals where the study occurred were aware that the study drugs had not been approved by the FDA and were investigational only);

(k) Failing to obtain and maintain accurate records showing all financial transactions from CareFusion to investigator Darouiche;

(l) Failing to maintain adequate records for the study. Neither the sponsor CareFusion nor the investigator Darouiche has revealed study documentation or records to allow for evaluation and validation of data presented in the ChloraPrep Study. When asked for details and records

regarding the 7 known deaths during the study, Darouiche stated that he did not have those records;

(m) Failing to select a qualified CareFusion monitor to ensure compliance with the study under an Investigative New Drug Application and instead selecting its Vice President of Medical Affairs Crosby, who lacked an advanced degree, who had no clinical background, and who had no training or experience to meet qualifications expected by a reasonable clinical organization; and

(n) Failing to report noncompliance with the FDA Form 1572 investigator statement signed by Darouiche (or the other 5 investigators).

109. The ChloraPrep Study is also invalid and off-label because investigator Darouiche has failed to meet any of the investigator obligations set forth under 21 CFR § 312 and the Statement of Investigator (FDA Form 1572), which he signed. Specifically, Darouiche continues to refuse to allow access to ChloraPrep Study records as required under 21 CFR § 312.62, including adverse event reports documenting patient deaths. During the Study, there were seven patient deaths, which were not reported to the sponsor by the investigator or by the sponsor to FDA as required by 21 CFR § 312.64.

110. The ChloraPrep Study is also invalid and off-label because there was no consistency as to how the ChloraPrep was administered from one patient to the next. Instead, Darouiche had ChloraPrep administered by different health care professionals to 409 patients in different operating rooms at 4 different hospitals and veterans' affairs

("VA") hospitals, *to wit*: Michael E Debakey Veterans Affairs Medical Center (Baylor College of Medicine), Houston, Texas; Ben Taub General Hospital, Houston, Texas; Veterans Affairs Medical Center and Medical College of Wisconsin, Milwaukee Wisconsin; Veterans Affairs Medical Center, Atlanta Georgia. Moreover, upon information and belief, the Government-Funded Plans covering the VA patients that were part of the ChloraPrep Study were billed for the ChloraPrep investigational ChloraPrep product that was provided by CareFusion to the hospital patients for free as part of the ChloraPrep Study.

111. The ChloraPrep Study is also invalid and off-label because CareFusion failed to secure the required contracts with Darouiche. To ensure that no improper payments or kickbacks are being made to the Study investigators, drug manufacturers that sponsor clinical studies must have contracts with the investigators that detail the scope of services that the investigator is to provide and the fair market value of those services ("FMV Contracts"). The investigator may not receive more than fair market value for services rendered. CareFusion failed to establish FMV Contracts with the investigators involved in the multicenter ChloraPrep Study. At no time did the Compliance Officer review or evaluate investigator grants or contracts for FMV. CareFusion paid millions of dollars to Darouiche and/or his private foundation in exchange for unspecified services for the ChloraPrep Study.

112. Shockingly, CareFusion continues to pay Darouiche and/or his private foundation for the ChloraPrep Study and the promotion of the Study and ChloraPrep products. It is using Darouiche as a sales vehicle by securing speaking engagements for him around the world to promote ChloraPrep products with the invalid and off-label

Study. CareFusion also pays for Darouiche to entertain doctors on these trips. These actions are in violation of statutes prohibiting kickbacks to doctors and investigators.

113. The fruits of the violative off-label ChloraPrep Study and large payments to Darouiche and/or his private foundation have been lucrative for CareFusion. Darouiche has stated he is converting VA Hospitals to ChloraPrep by using the violative and off-label ChloraPrep Study and making off-label statements that ChloraPrep prevents infections and reduces infection by 41%. His efforts on behalf of ChloraPrep are illegal and off-label. Darouiche is also illegally spending CareFusion money to entertain the subjects of his sales efforts. All of Darouiche's actions are on behalf of and at the direction of CareFusion, who bears the expense of Darouiche's travels and entertainment.

114. CareFusion provides Darouiche with a CareFusion administrative assistant to help him make travel plans.

115. In addition to securing VA hospital business from Darouiche's off-label marketing activities, the CareFusion sales force is actively using the invalid and off-label ChloraPrep Study to secure other state and private hospital contracts for ChloraPrep.

116. CareFusion refers to the invalid and off-label ChloraPrep Study as a "landmark study" in marketing and promotional materials, yet it is fully aware and has been advised by Relator that the Study violates the FDA rules and regulations.

117. In a second quarter 2010 CareFusion earnings conference call, Schlotterbeck stated, "Let me give you some recent and near-term examples of how we are innovating to reduce healthcare costs. First, you may have read about a groundbreaking study … Using our ChloraPrep product, the study showed a 41% reduction in surgical site infections over traditional povidone-iodine. Based on these

results, proper skin preparation using 2% chlorhexidine-alcohol has the potential to remove as much as $4 billion in healthcare costs in the US alone. Some hospitals are already declaring it the standard of care for certain surgical procedures. We have long believed ChloraPrep should be the standard of care in preparations [sic] prior to surgery or catheter insertions. To drive out growth, we are making investments to increase our sales force in the US and in key geographies worldwide."

118. CareFusion planned and executed a full-blown ad campaign and media blitz to get press coverage of the invalid and off-label ChloraPrep Study. On January 7, 2010, the Kansas City Star ran an article headlined "**Rx For Staph Infections**" and reported on the off-label Darouiche ChloraPrep Study. The article noted that the University of Kansas Hospital switched to ChloraPrep several years ago. The article reported Darouiche's finding that ChloraPrep "**cut all surgical site infections by 40 percent**." Darouiche stated in the article that the higher cost of the ChloraPrep product was "outweighed by the thousands saved by **preventing costly infections**." (Emphasis added.)

119. To date, there is no credible scientific evidence as required by § 505 of the FDCA supporting CareFusion's claims that ChloraPrep reduces infection, prevents infection and/or prevents infection by 41%.

CareFusion's Profits From Sales Generated with Off-label Statements and False and Misleading Statements

120. As set forth above, Enturia/Defendant Cardinal Health knowingly commercialized an unapproved product (ChloraPrep Hi-Lite Orange applicators) representing it as FDA-approved from October 2006 to June 2008. During that time, Enturia/Defendant Cardinal Health's profits almost doubled from $80 million in 2005 to

$140 million in 2007. This increase is attributable to the increase in sales induced by the illegal and fraudulent marketing of Hi-Lite Orange as if it were approved by the FDA.

121. The violative ChloraPrep Study has also increased Defendant CareFusion's sales of ChloraPrep. The forecasted increase in 2010 ChloraPrep revenue directly attributed to the ChloraPrep Study was $2.6 million.

122. ChloraPrep is a highly-lucrative drug, with sales soaring more than 50% annually since 2002 when the off-label promotional tactics were first used. The revenue reaped by Defendants for ChloraPrep was $80 million in 2005, $100 million in 2006, and $140 million in 2007. Projected ChloraPrep revenue for 2010 is $193 million.

123. The ChloraPrep Study directly caused CareFusion's sales and profits of ChloraPrep to increase. CareFusion sales representatives reported via e-mail to Senior Vice President Kelly, President Jain and others in the Infection Prevention Business Unit that the ChloraPrep Study opened doors to business that were previously shut. There are numerous accounts by sales reps that they were able to procure contracts for hundreds of thousands of dollars of ChloraPrep by using the ChloraPrep Study.

Defendant CareFusion Knows It Has An Off-Label Problem But Chooses to Continue Its Off-Label Promotional Tactics Because They Are Extremely Profitable

124. From the beginning of her employment with Defendant CareFusion as "Vice President of Regulatory Affairs for the Infection Prevention Business Unit" on September 17, 2009, Relator repeatedly raised concerns to CareFusion executives about the off-label and illegal marketing of ChloraPrep and the use of the ChloraPrep Study. At her own initiative, Relator prepared a report of her top seven compliance concerns that were patently apparent to her within a week of starting her position. Her number one concern was the off-label promotion of ChloraPrep for the prevention of infection. Her

number two concern was the non-compliance and off-label nature of the ChloraPrep Study. Throughout her employment, Relator explicitly warned top CareFusion executives that the use of the word "prevention" in the ChloraPrep Study and other promotional documents would constitute off-label promotion if distributed by sales representatives and included in other advertising materials. But instead of changing its illegal course, CareFusion terminated Relator and eliminated her position.

125. On October 1, 2009, Relator was told by her supervisor, Tom Rasnic, that in the CareFusion organization, Regulatory functions are "a service" and "there isn't an issue until the business unit determines there is an issue." Rasnic instructed Relator that it was important to be on the "same page" as the Business Unit. On October 7, 2009, Kelly took Relator to lunch and told her she needed to communicate any compliance concerns with him (Kelly) first, that she would have less interaction with her boss Rasnic and that she should speak to him (Kelly) first before addressing compliance issues with Rasnic.

126. On October 8, 2009, Relator, Jain, Kelly, Crosby, Baltezor and Creidenberg attended a management meeting at CareFusion offices in Leawood, Kansas. Rasnic attended the meeting by phone. During that meeting, Relator told the group that "infection prevention" claims and the ChloraPrep Study were off-label. Crosby responded by saying, "This is bullshit," and left the meeting at a break. After Crosby left and the others remained, Jain asked Relator who she thought she was. He told her that she should know better than to raise these issues. He also told her to follow the chain of command and if the Business Unit doesn't think it's a problem, then it's not a problem. In a later meeting, Jain stated that Relator was "building walls." Jain made it clear that

the Relator was a threat to the ChloraPrep sales and marketing plan, which was directly aligned with financial performance objectives at the highest level of management. Kelly also made it clear that Relator was a threat to ChloraPrep profits, telling her, "Preventing infection impacts my bottom line."

127. Jain and Kelly consistently stated in meetings that Regulatory was hindering their ability to compete and meet forecasted ChloraPrep sales numbers.

128. CareFusion executives recognized that its marketing of ChloraPrep was off-label and illegal but made the strategic decision to continue the off-label course of conduct because of the negative impact that compliance would have on profits, and because the rest of the industry was marketing in the same illegal off-label way.

129. Specifically, Kelly argued in response to Relator's concerns and in support of continuing their aggressive off-label practices that competitor off-label promotional activities justified the way ChloraPrep had been promoted historically and the way CareFusion should continue to promote ChloraPrep in the future. Kelly also argued that the risk of FDA action was "extremely minimal" based on the regulatory history of ChloraPrep's product category. Finally, Kelly argued that the off-label practices were too profitable to abandon. ChloraPrep products are approximately seven times more expensive than iodine, one alternative to ChloraPrep. Defendants used the off-label infection prevention and infection reduction claims to induce their customers to bite the bullet and pay much more for ChloraPrep than alternative pre-operative skin preparation products.

130. Despite its actual knowledge that its promotional activities were off-label, Defendant CareFusion continued its off-label practices because the competition was

doing it, it was very profitable for them, it justified their higher prices and it perceived the risk of FDA enforcement as "extremely minimal."

THE TARGET OF CAREFUSION'S OFF-LABEL AND ILLEGAL MARKETING WAS GOVERNMENT-FUNDED PLANS

131. A significant percentage of the ChloraPrep charges were paid for, directly or indirectly, by the United States Government in the form of reimbursements through federally-funded state Medicaid programs, Medicare programs, military health care programs, government employee health care programs, and military treatment facilities, all of which were unaware of the falsity of the claims and which relied on the accuracy thereof.

132. Upon information and belief, ChloraPrep was also paid for, directly or indirectly, by the United States Government in the form of reimbursements through military health care program(s) in place in VA hospitals and other military health care programs throughout the country and world, which were unaware of the falsity of the claims and which relied on the accuracy thereof.

133. Upon information and belief, Defendants caused the submission of claims for off-label charges to federally and state-funded programs in almost all fifty states and the District of Columbia.

134. In 2005, over 4,000 of 5,800 hospitals in the United States used ChloraPrep in some form, and virtually every hospital in the Kansas City area uses ChloraPrep.

135. Defendant CareFusion currently has over 100 sales managers and sales representatives employing CareFusion's off-label and deceptive marketing tactics on

doctors, nurses, surgery centers and the Infection Prevention Units of over 4,000 hospitals.

136. Defendants specifically targeted government funds with their illegal off-label marketing claims. Relator was part of monthly Leadership Meetings for the Infection Prevention Business Unit. In those meetings, Senior Vice President Mike Kelly and others routinely discussed how sales and marketing should target their infection prevention and reduction marketing efforts at Medicare, as well as funds dedicated for "infection control" by Health and Human Services ("HHS") and Centers for Medicare and Medicaid Services ("CMS") and surgery centers and hospitals that were reimbursed by CMS. 6

137. Government healthcare facilities were also targets of Defendants' infection prevention and reduction claims. In June 2011, Defendant CareFusion hosted an exhibit at the Military Healthcare Convention and Conference in San Antonio, Texas.

138. Defendants also used Darouiche to make illegal marketing claims about reducing infection rates to VA Hospitals, as well as to other government healthcare facilities and private healthcare facilities that submitted claims to Medicare and Medicaid for reimbursement for ChloraPrep costs. Darouiche recently claimed that using the "more expensive" ChloraPrep reduces the rate of SSIs by "40 percent," as compared to "cheaper antiseptics," and "the cost savings [to hospitals] are anywhere between hundreds of thousands to a few million dollars."

139. Upon information and belief, from at least 2002 until the present, 100% of the ChloraPrep charges submitted to Government-Funded Plans for reimbursement and

invoices submitted to military treatment facilities were the fruits of off-label marketing practices by Defendants.

140. One in three Americans is covered by a Government-Funded Plan.

141. There are approximately 30 million surgeries performed every year.

142. The cost to the Government-Funded Plans as a result of Defendants' illegal marketing activities was high. The pricing for the 10 different ChloraPrep products on the market ranges from $1.75 to $12.07, with an average price of $6.91. Hi-Lite Orange, the best seller in the ChloraPrep line, sells for $12.07 per 26 ml applicator. Prices for alternative pre-operative skin preparation products are much less. Defendants justified their premium prices to their customers with their off-label marketing claims. The annual estimated unit sale for ChloraPrep is 1.5 million units. For fiscal year 2010, revenue from the ChloraPrep product line was projected to be $193 million.

143. Upon information and belief, it is estimated that millions of dollars were paid by Government-Funded Plans and military treatment facilities (including VA hospitals), and were a result of Defendants' illegal marketing scheme from at least 2002 to the present.

144. Defendant CareFusion has not taken the necessary and appropriate steps to train its employees, including its sales representatives, about compliance issues. CareFusion conducts no compliance training sessions, has no compliance employee manual and has no compliance committee.

145. Defendant CareFusion is currently under a Consent Decree for illegal quality systems activities.

COUNT I:
Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)
(Off-Label Marketing)

146. Relator incorporates by reference paragraphs 1 through 145 as if set forth fully here.

147. A significant percentage of patients to whom ChloraPrep was administered for an off-label purpose are persons whose FDA-regulated drugs are paid for in whole or in part by state-administered medical assistance programs that receive reimbursement from the United States Government, including Medicaid, Medicare, military health care programs and government employee health care programs (collectively "Government-Funded Plans").

148. Defendants induced the submission of off-label ChloraPrep charges to Government-Funded Plans for reimbursement. The induced submission of such charges impliedly certified compliance with Medicaid, Medicare and other government statutes and regulations.

149. The promoted use for the ChloraPrep charges was not approved by the FDA or recognized as a medically accepted use by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, the DRUGDEX Information System, the American Medical Association Drug Evaluations, the National Formulary, the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies, or supported by any valid scientific study published in any peer-reviewed medical literature, or, upon information and belief, approved by any hospital pharmacy and drug therapeutics medical staff committee.

150. Defendants submitted or caused to be submitted claims to the United States Government for payment or approval.

151. Such claims were false or fraudulent.

152. As outlined above in paragraphs 14-145, Defendants perpetuated fraud on the government and used their illegal marketing claims to induce customers to pay more for ChloraPrep products than alternative drug products.

153. Defendants had actual knowledge, and/or acted in deliberate ignorance of the truth or falsity of the information, and/or recklessly disregarded a risk, that charges for off-label and unapproved ChloraPrep were not eligible for reimbursement from Government-Funded Plans as evidenced by the actions outlined above in paragraphs 14-145. In addition, Defendants knew or should have known of the passage of 42 U.S.C. § 1396r-8 and 42 U.S.C. §1395x(t)(1) and the statutory limitations found therein on government reimbursement for drugs. In addition, Defendants have entered into Medicaid and Medicare Rebate Agreements and other contracts with the United States whereby Defendants agreed to abide by all statutory and regulatory regulations and that specifically informed Defendants what constituted covered drugs under government-funded plans and that notified Defendants that drugs that were not used for a medically accepted use were not covered drugs. Notwithstanding Defendants' knowledge that the charges for ChloraPrep that Defendants promoted off-label was not eligible for reimbursement from Government-Funded Plans, Defendants knowingly and intentionally took steps to increase the charges for ChloraPrep submitted to Government-Funded Plans. But for Defendants' promotion of off-label uses for all products in the ChloraPrep line and Defendants' promotion of ChloraPrep Hi-Lite Orange and Triple

Swab with no FDA approval whatsoever, the ineligible and inflated claims for payment of ChloraPrep charges would have never been filed because they were not in compliance with Medicaid, Medicare and other government statutes and regulations.

154. Defendants acted knowingly, either with actual knowledge that the information they were using to market ChloraPrep was off-label and unapproved and that ChloraPrep charges as a result of its off-label and unapproved product marketing efforts were not eligible for reimbursement from Government-Funded Plans (as evidenced by the actions outlined above in paragraphs 14 through 145), or in deliberate ignorance or reckless disregard of the truth or falsity of the information.

155. Every off-label ChloraPrep charge caused by Defendants' off-label marketing practices and submitted to Government-Funded Plans for reimbursement (both separately and as part of a DRG or CPT Code) is a false claim caused by Defendants for purposes of 31 U.S.C. § 3729 (a)(1).

156. Pursuant to 31 U.S.C. §§ 3729 (a)(7) and 3730, Defendants are liable to the United States Government for actual damages, trebled, a civil penalty of not less than $5,500 and not more than $11,000 for each off-label or unapproved product commercialization charge for ChloraPrep reimbursed by a Government-Funded Plan, plus attorneys' fees and costs. The highest possible penalties are appropriate in this case in light of the actual knowledge of Defendants. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully requests that the Court enter judgment against Defendants and in favor of the United States as follows:

a. that the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Second Amended Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Second Amended Complaint;

e. that Relator be awarded the maximum amount allowed to her pursuant to the False Claims Act and the state False Claims Acts set forth below;

f. that Relator be awarded the maximum amount allowed to her of any portion of a judgment or settlement fund that goes to any state government; and

g. that this Court award such other and further relief as it deems proper.

COUNT II:
Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)
(Knowing Breach of Government Contracts)

157. Relator incorporates by reference paragraphs 1 through 156 as if set forth fully here.

158. From at least 2005 and continuing in the present, Defendants enjoyed lucrative and, upon information and belief, exclusive government contracts with Military Treatment Facilities and VA Hospitals for ChloraPrep. During that time, 100% of the contract payments from the government to Defendants was with Defendants' express agreement that they would abide by federal laws and regulations, including those of the FDA.

159. Defendants failed to abide by federal laws and regulations, including those of the FDA, when they sold HiLite Orange and Triple Swab ChloraPrep products to government-owned healthcare facilities without the required FDA approval.

160. Defendants failed to abide by federal laws and regulations, including those of the FDA, when they induced government-owned healthcare facilities to contract for and pay more for ChloraPrep products than less expensive alternative pre-operative skin preparation products with off-label claims of infection prevention and infection reduction, as outlined extensively above in paragraphs 14-145.

161. Selling non-FDA compliant drugs and using illegal off-label marketing claims to sell drugs to government-owned healthcare facilities was and is an on-going breach of Defendants' obligations under the regulations and contracts with the Government.

162. Defendants knew or should have known they were breaching their contracts with the Government.

163. Defendants submitted or caused to be submitted claims to the United States Government for payment or approval.

164. Such claims were false or fraudulent.

165. As outlined above in paragraphs 14-145, Defendants perpetuated fraud on the government. They targeted government-owned healthcare facilities with their off-label claims of prevention and reduction of several types of infections, including Hospital-Acquired-Infections, and thereby induced these government customers to pay the premium price at which Defendants sold ChloraPrep.

166. Defendants had actual knowledge, and/or acted in deliberate ignorance of the truth or falsity of the information, and/or recklessly disregarded a risk, that non-FDA approved drugs and drugs sold with off-label claims of infection prevention and infection reduction were not eligible for remuneration from contracts with government-owned healthcare facilities. Notwithstanding Defendants' knowledge that the government contracts for ChloraPrep required compliance with FDA rules and regulations, Defendants knowingly and intentionally took steps to contract with government-owned healthcare facilities (VA Hospitals and military hospitals and other military treatment facilities) for ChloraPrep. If the government-owned healthcare facilities knew that ChloraPrep violated FDA rules and regulations, they would not have contracted and paid for those drugs.

167. Defendants acted knowingly, either with actual knowledge that they were breaching their government contracts for ChloraPrep (as evidenced by the actions and

evidence outlined above in paragraphs 14 through 145), or in deliberate ignorance or reckless disregard of the truth or falsity of the information.

168. Every contractual payment by a government-owned healthcare facility for ChloraPrep is a false claim caused by Defendants for purposes of 31 U.S.C. § 3729 (a)(1).

169. Pursuant to 31 U.S.C. §§ 3729 (a)(7) and 3730, Defendants are liable to the United States Government for actual damages, trebled, a civil penalty of not less than $5,500 and not more than $11,000 for each contract payment for a ChloraPrep product from a government-owned healthcare facility, plus attorneys' fees and costs. The highest possible penalties are appropriate in this case in light of the actual knowledge of Defendants that they were breaching their government contracts. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal laws.

WHEREFORE, Relator respectfully requests that the Court enter judgment against Defendants and in favor of the United States as follows:

h. that the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Second Amended Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

i. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States and/or its grantees;

j. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

k. that the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Second Amended Complaint;

l. that Relator be awarded the maximum amount allowed to her pursuant to the False Claims Act and the state False Claims Acts set forth below;

m. that Relator be awarded the maximum amount allowed to her of any portion of a judgment or settlement fund that goes to any state government; and

n. that this Court award such other and further relief as it deems proper.

COUNT III:
Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)
(Illegal Kickbacks)

170. Relator incorporates by reference paragraphs 1 through 169 as if set forth fully here.

171. Defendants paid money to Rabih Darouiche, M.D., and other doctors and investigators to induce the submission of ChloraPrep charges to Government-Funded Plans for reimbursement and government healthcare facilities with off-label marketing claims.

172. Under 42 U.S.C. § 1320a-7b(b), whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,500 or imprisoned for not more than five years, or both.

173. Defendants submitted or caused to be submitted claims to the United States Government for payment or approval.

174. Such claims were false or fraudulent.

175. Defendants had actual knowledge, and/or acted in deliberate ignorance of the truth or falsity of the information, and/or recklessly disregarded a risk that ChloraPrep charges to the government were as a result of illegal kickbacks when they provided Rabih Darouiche, M.D. (and upon information and belief other doctors and/or investigators) with remuneration so he would arrange for or recommend to VA Hospitals and other healthcare facilities to purchase or order an item (ChloraPrep) for which payment was made in whole or in part under a Federal health care program and when Defendants, upon information and belief, provided Rabih Darouiche, M.D., with free ChloraPrep products, which were charged to surgery patients on Government-Funded Plans, which caused Government-Funded Plans to make reimbursements for those free ChloraPrep products.

Defendants also knowingly and intentionally took steps to pay kickbacks to Darouiche and, upon information and belief, other doctors and investigators, to induce ChloraPrep use with illegal and off-label claims of infection prevention and reduction, which resulted in charges to be submitted to Government-Funded Plans. But for Defendants' illegal kickbacks, the ineligible claims for payment of ChloraPrep would have never been filed or paid because they were not in compliance with government statutes and regulations.

176. Defendants acted knowingly, either with actual knowledge that the kickbacks they were making to doctors and investigators to induce ChloraPrep sales and that ChloraPrep charges resulting from their illegal kickbacks were not eligible for reimbursement from Government-Funded Plans, as evidenced by the documents and actions outlined above in paragraphs 14 through 145, or in deliberate ignorance or reckless disregard of the truth or falsity of the information.

177. Every ChloraPrep charge caused by Defendants' illegal kickbacks and submitted to Government-Funded Plans for reimbursement is a false claim caused by Defendants for purposes of 31 U.S.C. § 3729 (a)(1).

178. Pursuant to 31 U.S.C. §§ 3729 (a)(7) and 3730, Defendants are liable to the United States Government for actual damages, trebled, a civil penalty of not less than $5,500 and not more than $11,000 for each ChloraPrep charge caused by illegal kickbacks and reimbursed by a Government-Funded Plan, plus attorneys' fees and costs. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal laws.

WHEREFORE, Relator respectfully requests that the Court enter judgment against Defendants and in favor of the United States as follows:

a. that the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Second Amended Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendant CareFusion presented to the United States and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Second Amended Complaint;

e. that Relator be awarded the maximum amount allowed to her pursuant to the False Claims Act and the state False Claims Acts set forth below;

f. that Relator be awarded the maximum amount allowed to her of any portion of a judgment or settlement fund that goes to any state government; and

g. that this Court award such other and further relief as it deems proper.

COUNT IV:
Violation of State Law: Arkansas Medicaid Fraud Claims Act

179. Relator, on behalf of herself and the State of Arkansas, incorporates by reference paragraphs 1 through 178 as if set forth fully here.

180. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

181. Medicaid is jointly funded by the federal and state governments.

182. Defendants submitted or caused to be submitted claims to the Arkansas Medicaid and/or other government-funded system for payment or approval.

183. Pursuant to the Arkansas Medicaid Fraud False Claims Act, codified at Ark. Stat. Ann. § 20-77-901, *et seq*., Defendants are liable to the United States/State of Arkansas for three times the amount of damages that the United States/State of Arkansas sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Arkansas as follows:

a. that the United States/State of Arkansas be awarded damages in the amount of three times the damages sustained by the United

States/State of Arkansas because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Arkansas and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Arkansas Medicaid Fraud False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Arkansas Medicaid Fraud False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT V:
Violation of State Law: California False Claims Act

184. Relator, on behalf of herself and the State of California, incorporates by reference paragraphs 1 through 183 as if set forth fully here.

185. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

186. Medicaid is jointly funded by the federal and state governments.

187. Defendants submitted or caused to be submitted claims to the California Medicaid system (also known as "MediCal") and/or other state-funded system for payment or approval.

188. Pursuant to the California False Claims Act, codified at California Government Code § 12650, *et seq.*, Defendants are liable to the United States/State of California for three times the amount of damages that the United States/State of California or political subdivision sustained, costs of the action and a penalty of up to $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws. The amount in controversy here exceeds $500.

WHEREFORE, Relator respectfully requests that the Court enter judgment against Defendants and in favor of the United States/State of California as follows:

a. that the United States/State of California be awarded damages in the amount of three times the damages sustained by the United States/State of California because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of California and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the California False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the California False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT VI:
Violation of State Law: Colorado Medical Assistance Act

189. Relator, on behalf of herself and the State of Colorado, incorporates by reference paragraphs 1 through 188 as if set forth fully here.

190. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

191. Medicaid is jointly funded by the federal and state governments.

192. Defendants submitted or caused to be submitted claims to the Colorado Medicaid system and/or other government-funded system for payment or approval.

193. Pursuant to the Colorado Medical Assistance Act, codified at CO. STAT. §§ 25.5-4-101, 25.5-4-304, *et seq.*, Defendants are liable to the United States/State of Colorado for full restitution, two times the amount of damages that the United States/State of Colorado sustained and a civil penalty of $5,500 for each false claim, costs of the action and attorneys' fees. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also

appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Colorado as follows:

a. that the United States/State of Colorado be awarded damages in the amount of two times the damages sustained by the United States/State of Colorado because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $5,500 for each and every false claim that Defendants presented to the United States/State of Colorado and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Colorado Medical Assistance Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Colorado Medical Assistance Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT VII:
Violation of State Law: Connecticut Health Insurance Fraud Act

194. Relator, on behalf of herself and the State of Connecticut, incorporates by reference paragraphs 1 through 193 as if set forth fully here.

195. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

196. Medicaid is jointly funded by the federal and state governments.

197. Defendants submitted or caused to be submitted claims to the Connecticut Medicaid system and/or other government-funded system for payment or approval.

198. Pursuant to the Connecticut False Claims Act and/or Health Care False Claims Act and/or Health Insurance Fraud Act, codified at Conn. Stat. Ann. §§17b-301a, *et seq.* and/or §§ 53-440, *et seq.*, Defendants are liable to the United States/State of Connecticut for three times the amount of damages that the United States/State of Arkansas sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Connecticut as follows:

g. that the United States/State of Connecticut be awarded damages in the amount of three times the damages sustained by the United

States/State of Connecticut because of the false claims alleged within this Second Amended Complaint;

h. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Connecticut and/or its grantees;

i. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

j. that the Court grant permanent injunctive relief to prevent any recurrence of the Connecticut False Claims Act and/or Health Care False Claims Act and/or Health Insurance Fraud Act for which redress is sought in this Second Amended Complaint;

k. that the Relator be awarded the maximum amount allowed to her pursuant to the Connecticut False Claims Act and/or Health Care False Claims Act and/or Health Insurance Fraud Act; and

l. that this Court award such other and further relief as it deems proper.

COUNT VIII:
Violation of State Law: Delaware False Claims and Reporting Act

199. Relator, on behalf of herself and the State of Delaware, incorporates by reference paragraphs 1 through 198 as if set forth fully here.

200. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within

such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

201. Medicaid is jointly funded by the federal and state governments.

202. Defendants submitted or caused to be submitted claims to the Delaware Medicaid system and/or other government-funded system for payment or approval.

203. Pursuant to the Delaware False Claims and Reporting Act, codified at Del. Code Ann. tit. 6, § 1201, *et seq*., Defendants are liable to the United States/State of Delaware for three times the amount of damages that the United States/state government sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully requests that the Court enter judgment against Defendants and in favor of the United States/State of Delaware as follows:

a. that the United States/State of Delaware be awarded damages in the amount of three times the damages sustained by the United States/State of Delaware because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Delaware and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Delaware False Claims and Reporting Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Delaware False Claims and Reporting Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT IX:
Violation of District of Columbia False Claims Act

204. Relator, on behalf of herself and the District of Columbia, incorporates by reference paragraphs 1 through 203 as if set forth fully here.

205. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

206. Medicaid is jointly funded by the federal and state governments.

207. Defendants submitted or caused to be submitted claims to the District of Columbia Medicaid system and/or other government-funded system for payment or approval.

208. Pursuant to the District of Columbia False Claims Act, codified at D.C. Code Ann. § 2-308.03, *et seq.*, Defendants are liable to the United States/District of

Columbia for three times the amount of damages that the United States/District of Columbia sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/District of Columbia as follows:

a. that the United States/District of Columbia be awarded damages in the amount of three times the damages sustained by the United States/District of Columbia because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/District of Columbia and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the District of Columbia False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the District of Columbia False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT X:
Violation of State Law: Florida False Claims Act

209. Relator, on behalf of herself and the State of Florida, incorporates by reference paragraphs 1 through 208 as if set forth fully here.

210. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

211. Medicaid is jointly funded by the federal and state governments.

212. Defendants submitted or caused to be submitted claims to the Florida Medicaid system and/or other government-funded system for payment or approval.

213. Pursuant to the Florida False Claims Act, codified at Fla. Stat. § 68.081, *et seq.*, Defendants are liable to the United States/State of Florida for three times the amount of damages that the United States/State of Florida sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Florida as follows:

a. that the United States/State of Florida be awarded damages in the amount of three times the damages sustained by the United

States/State of Florida because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Florida and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Florida False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Florida False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XI:
Violation of State Law: Georgia False Medicaid Claims Act

214. Relator, on behalf of herself and the State of Georgia, incorporates by reference paragraphs 1 through 213 as if set forth fully here.

215. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

216. Medicaid is jointly funded by the federal and state governments.

217. Defendants submitted or caused to be submitted claims to the Georgia Medicaid system and/or other government-funded system for payment or approval.

218. Pursuant to the Georgia False Medicaid Claims Act, codified at GA. STAT. §§ 49-4-168, *et seq*., Defendants are liable to the United States/State of Georgia for three times the amount of damages that the United States/State of Georgia sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Georgia as follows:

a. that the United States/State of Georgia be awarded damages in the amount of three times the damages sustained by the United States/State of Georgia because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 for each and every false claim that Defendants presented to the United States/State of Georgia and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Georgia False Medicaid Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Georgia False Medicaid Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XII:
Violation of State Law: Hawaii False Claims Act

219. Relator, on behalf of herself and the State of Hawaii, incorporates by reference paragraphs 1 through 218 as if set forth fully here.

220. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

221. Medicaid is jointly funded by the federal and state governments.

222. Defendants submitted or caused to be submitted claims to the Hawaii Medicaid system and/or other government-funded system for payment or approval.

223. Pursuant to the Hawaii False Claims Act, codified at Haw. Rev. Stat. § 661-21, *et seq.*, Defendants are liable to the United States/State of Hawaii for three times the amount of damages that the United States/State of Hawaii sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this

case to send a message to Defendants' industry that they must abide by federal and state laws. The amount in controversy exceeds $500.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Hawaii as follows:

a. that the United States/State of Hawaii be awarded damages in the amount of three times the damages sustained by the United States/State of Hawaii because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Hawaii and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Hawaii False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Hawaii False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XIII:
Violation of Illinois False Claims Act

224. Relator, on behalf of herself and the State of Illinois, incorporates by reference paragraphs 1 through 223 as if set forth fully here.

225. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

226. Medicaid is jointly funded by the federal and state governments.

227. Defendants submitted or caused to be submitted claims to the Illinois Medicaid system and/or other government-funded system for payment or approval.

228. Pursuant to the Illinois False Claims Act (formerly known as the Illinois Whistleblower Reward and Protection Act, codified at Il. Comp. Stat. Ann. § 175/1, *et seq.*, Defendants are liable to the United States/State of Illinois for three times the amount of damages that the United States/State of Illinois sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Illinois as follows:

a. that the United States/State of Illinois be awarded damages in the amount of three times the damages sustained by the United

States/State of Illinois because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Illinois and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Illinois Whistleblower Reward and Protection Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Illinois Whistleblower Reward and Protection Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XIV:
Violation of State Law: Indiana False Claims and Whistleblower Protection Act

229. Relator, on behalf of herself and the State of Indiana, incorporates by reference paragraphs 1 through 228 as if set forth fully here.

230. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

231. Medicaid is jointly funded by the federal and state governments.

232. Defendants submitted or caused to be submitted claims to the Indiana Medicaid system and/or other government-funded system for payment or approval.

233. Pursuant to the Indiana False Claims and Whistleblower Protection Act, codified at Indiana Code 5-11-5.5, *et seq.*, Defendants are liable to the United States/State of Indiana for three times the amount of damages that the state sustained, costs of the action and a penalty of not less than $5,500 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Indiana as follows:

a. that the United States/State of Indiana be awarded damages in the amount of three times the damages sustained by the United States/State of Indiana because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of not less than $5,500 and the maximum allowable by law be imposed for each and every false claim that Defendants presented to the United States/State of Indiana and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Indiana False Claims and Whistleblower Protection Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Indiana False Claims and Whistleblower Protection Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XV:
Violation of State Law: Louisiana False Claims Act

234. Relator, on behalf of herself and the State of Louisiana Medical Assistance Programs, incorporates by reference paragraphs 1 through 233 as if set forth fully here.

235. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

236. Medicaid is jointly funded by the federal and state governments.

237. Defendants submitted or caused to be submitted claims to the Louisiana Medicaid system and/or other government-funded system for payment or approval.

238. Pursuant to the Louisiana False Claims Act and/or the Louisiana Medical Assistance Programs Integrity Law, codified at La. Rev. Stat. Ann. § 46:437.1, *et seq.*, Defendants are liable to the United States/State of Louisiana Medical Assistance Programs for three times the amount of damages that the United States/State of Louisiana

Medical Assistance Programs sustained, costs of the action and a penalty of not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Louisiana Medical Assistance Programs as follows:

a. that the United States/State of Louisiana Medical Assistance Programs be awarded damages in the amount of three times the damages sustained by the United States/State of Louisiana because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Louisiana Medical Assistance Programs and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Louisiana False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Louisiana False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XVI:
Violation of State Law: Maryland False Health Claims Act

239. Relator, on behalf of herself and the State of Maryland, incorporates by reference paragraphs 1 through 238 as if set forth fully here.

240. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

241. Medicaid is jointly funded by the federal and state governments.

242. Defendants submitted or caused to be submitted claims to the Maryland Medicaid system and/or other government-funded system for payment or approval.

243. Pursuant to the Maryland False Health Claims Act, as enacted by 2010 Maryland Laws Ch. 4 (S.B. 279), Defendants are liable to the United States/State of Maryland for three times the amount of damages that the United States/Maryland sustained, costs of the action and a penalty of $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Maryland as follows:

a. that the United States/State of Maryland be awarded damages in the amount of three times the damages sustained by the United States/State of

Maryland because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Maryland and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Maryland False Health Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Maryland False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XVII:
Violation of State Law: Massachusetts False Claims Act

244. Relator, on behalf of herself and the State of Massachusetts, incorporates by reference paragraphs 1 through 243 as if set forth fully here.

245. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

246. Medicaid is jointly funded by the federal and state governments.

247. Defendants submitted or caused to be submitted claims to the Massachusetts Medicaid system and/or other government-funded system for payment or approval.

248. Pursuant to the Massachusetts False Claims Act, codified at Mass. Ann. Laws Ch. 12, § 5(A), *et seq.*, Defendants are liable to the United States/State of Massachusetts for three times the amount of damages that the United States/State of Massachusetts sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Massachusetts as follows:

a. that the United States/State of Massachusetts be awarded damages in the amount of three times the damages sustained by the United States/State of Massachusetts because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Massachusetts and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Massachusetts False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Massachusetts False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XVIII:
Violation of State Law: Michigan Medicaid False Claims Act

249. Relator, on behalf of herself and the State of Michigan, incorporates by reference paragraphs 1 through 248 as if set forth fully here.

250. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

251. Medicaid is jointly funded by the federal and state governments.

252. Defendants submitted or caused to be submitted claims to the Michigan Medicaid system and/or other government-funded system for payment or approval.

253. Pursuant to the Michigan Medicaid False Claims Act, codified at MI Public Act 337, MCL § 400.611, *et seq*., Defendants are liable to the United States/State of Michigan for three times the amount of damages that the United States/State of Michigan sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also

appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Michigan as follows:

a. that the United States/State of Michigan be awarded damages at the highest rate allowable by law because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Massachusetts and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Michigan Medicaid False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Michigan Medicaid False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XIX:
Violation of State Law: Minnesota False Claims Act

254. Relator, on behalf of herself and the State of Minnesota, incorporates by reference paragraphs 1 through 253 as if set forth fully here.

255. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

256. Medicaid is jointly funded by the federal and state governments.

257. Defendants submitted or caused to be submitted claims to the Minnesota Medicaid Act system and/or other government-funded system for payment or approval.

258. Pursuant to the Minnesota False Claims Act, codified at Minn. Stat. §15C.01, *et seq.*, Defendants are liable to the United States/State of Minnesota for three times the amount of damages that the United States/State of Minnesota sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Minnesota as follows:

a. that the United States/State of Minnesota be awarded damages in the amount of three times the damages sustained by the United States/State of Minnesota because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Minnesota and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Minnesota False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Minnesota False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XX:
Violation of State Law: Missouri Health Care Payment Fraud and Abuse Act

259. Relator, on behalf of herself and the State of Missouri, incorporates by reference paragraphs 1 through 258 as if set forth fully here.

260. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

261. Medicaid is jointly funded by the federal and state governments.

262. Defendants submitted or caused to be submitted claims to the Missouri Medicaid system and/or other government-funded system for payment or approval.

263. Pursuant to the Missouri Health Care Payment Fraud and Abuse Act, codified at Mo. Rev. Stat. §191.900, *et seq*., Defendants are liable to the United States/State of Missouri for three times the amount of damages that the United States/State of Missouri sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Missouri as follows:

g. that the United States/State of Missouri be awarded damages in the amount of three times the damages sustained by the United States/State of Missouri because of the false claims alleged within this Second Amended Complaint;

h. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Missouri and/or its grantees;

i. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

j. that the Court grant permanent injunctive relief to prevent any recurrence of the Missouri Health Care Payment Fraud and Abuse Act for which redress is sought in this Second Amended Complaint;

k. that the Relator be awarded the maximum amount allowed to her pursuant to the Missouri Health Care Payment Fraud and Abuse Act; and

l. that this Court award such other and further relief as it deems proper.

COUNT XXI:
Violation of State Law: Montana False Claims Act

264. Relator, on behalf of herself and the State of Montana, incorporates by reference paragraphs 1 through 263 as if set forth fully here.

265. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

266. Medicaid is jointly funded by the federal and state governments.

267. Defendants submitted or caused to be submitted claims to the Montana Medicaid system and/or other government-funded system for payment or approval.

268. Pursuant to the Montana False Claims Act, codified at Mont. Code Ann. § 17-8-401, *et seq.*, Defendants are liable to the United States/State of Montana for not less than two times and not more than three times the amount of damages that the United States/State of Montana sustained, costs of the action and a penalty of not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Montana as follows:

a. that the United States/State of Montana be awarded damages in the amount of three times the damages sustained by the United States/State of Montana because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Montana and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Montana False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Montana False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXII:
Violation of State Law: Nevada Submission of False Claims to State or Local Government

269. Relator, on behalf of herself and the State of Nevada, incorporates by reference paragraphs 1 through 268 as if set forth fully here.

270. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within

such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

271. Medicaid is jointly funded by the federal and state governments.

272. Defendants submitted or caused to be submitted claims to the Nevada Medicaid system and/or other government-funded system for payment or approval.

273. Pursuant to the Nevada Submission of False Claims to State or Local Government, codified at Nev. Rev. Stat. § 357.010, *et seq.*, Defendants are liable to the United States/State of Nevada for three times the amount of damages that the United States/State of Nevada sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Nevada as follows:

a. that the United States/State of Nevada be awarded damages in the amount of three times the damages sustained by the United States/State of Nevada because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Nevada and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Nevada Submission of False Claims to State or Local Government for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Nevada Submission of False Claims to State or Local Government; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXIII:
Violation of State Law: New Hampshire False Claims Act

274. Relator, on behalf of herself and the State of New Hampshire, incorporates by reference paragraphs 1 through 273 as if set forth fully here.

275. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

276. Medicaid is jointly funded by the federal and state governments.

277. Defendants submitted or caused to be submitted claims to the New Hampshire Medicaid system and/or other government-funded system for payment or approval.

278. Pursuant to the New Hampshire False Claims Act, codified at New Hampshire § 167:61-b, *et seq.*, Defendants are liable to the United States/State of New Hampshire for three times the amount of damages that the United States/State of New Hampshire sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws. The amount in controversy here exceeds $5,500.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of New Hampshire as follows:

a. that the United States/State of New Hampshire be awarded damages in the amount of three times the damages sustained by the United States/State of New Hampshire because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of New Hampshire and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the New Hampshire False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the New Hampshire False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXIV:
Violation of State Law: New Jersey False Claims Act

279. Relator, on behalf of herself and the State of New Jersey, incorporates by reference paragraphs 1 through 278 as if set forth fully here.

280. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

281. Medicaid is jointly funded by the federal and state governments.

282. Defendants submitted or caused to be submitted claims to the New Jersey Medicaid system and/or other government-funded system for payment or approval.

283. Pursuant to the New Jersey False Claims Act, codified at NJ Stat. § 2A:32C-1, , *et seq.,* Defendants are liable to the United States/State of New Jersey for three times the amount of damages that the United States/State of New Jersey sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of New Jersey as follows:

a. that the United States/State of New Jersey be awarded damages in the amount of three times the damages sustained by the United States/State of New Jersey because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of New Jersey and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the New Jersey False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the New Jersey False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXV:
Violation of State Law: New Mexico Medicaid False Claims Act and New Mexico Fraud Against Taxpayers Act

284. Relator, on behalf of herself and the State of New Mexico, incorporates by reference paragraphs 1 through 283 as if set forth fully here.

285. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

286. Medicaid is jointly funded by the federal and state governments.

287. Defendants submitted or caused to be submitted claims to the New Mexico Medicaid system and/or other government-funded system for payment or approval.

288. Pursuant to the New Mexico Medicaid False Claims Act, codified at N.M.S.A. 27-14-1, *et seq*., and/or the New Mexico Fraud Against Taxpayers Act, codified at N.M.S.A. 44-9-1, *et seq*., Defendants are liable to the United States/State of New Mexico for three times the amount of damages that the United States/state sustained, costs of the action and a civil recovery for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of New Mexico as follows:

a. that the United States/State of New Mexico be awarded damages in the amount of three times the damages sustained by the United States/State of New Mexico because of the false claims alleged within this Second Amended Complaint;

b. that maximum civil recoveries allowed by law for each and every false claim that Defendants presented to the United States/State of New Mexico and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the New Mexico Medicaid False Claims Act and/or the New Mexico Fraud Against Taxpayers Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the New Mexico Medicaid False Claims Act New Mexico Fraud Against Taxpayers Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXVI:
Violation of State Law: New York False Claims Act

289. Relator, on behalf of herself and the State of New York, incorporates by reference paragraphs 1 through 288 as if set forth fully here.

290. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

291. Medicaid is jointly funded by the federal and state governments.

292. Defendants submitted or caused to be submitted claims to the New York Medicaid system and/or other government-funded system for payment or approval.

293. Pursuant to the New York False Claims Act, codified at NY State. Fin. Law, ch. 13 §§ 187-194, Defendants are liable to the United States/State of New York for three times the amount of damages that the United States/State of New York sustained, costs of the action and a penalty of not less than $6,000 and not more than $12,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws. Defendants each has an income over $1 million and the harm to the State of New York exceeds $350,000.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of New York as follows:

a. that the United States/State of New York be awarded damages in the amount of three times the damages sustained by the United States/State of New York because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $12,000 be imposed for each and every false claim that Defendants presented to the United States/State of New York and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the New York State False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the New York State False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXVII:
Violation of State Law: North Carolina False Claims Act

294. Relator, on behalf of herself and the State of North Carolina, incorporates by reference paragraphs 1 through 293 as if set forth fully here.

295. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

296. Medicaid is jointly funded by the federal and state governments.

297. Defendants submitted or caused to be submitted claims to the North Carolina Medicaid system and/or other government-funded system for payment or approval.

298. Pursuant to the North Carolina False Claims Act, S.L. 2009-554/HB 1135, Defendants are liable to the United States/State of North Carolina for three times the amount of damages that the United States/State of North Carolina sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this

case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of North Carolina as follows:

a. that the United States/State of North Carolina be awarded damages in the amount of three times the damages sustained by the United States/State of North Carolina because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of North Carolina and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the North Carolina False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the North Carolina False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXVIII:
Violation of State Law: Oklahoma Medicaid False Claims Act

299. Relator, on behalf of herself and the State of Oklahoma, incorporates by reference paragraphs 1 through 298 as if set forth fully here.

300. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

301. Medicaid is jointly funded by the federal and state governments.

302. Defendants submitted or caused to be submitted claims to the Oklahoma Medicaid system and/or other government-funded system for payment or approval.

303. Pursuant to the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053, *et seq.*, Defendants are liable to the United States/State of Oklahoma for three times the amount of damages that the United States/State of Oklahoma sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Oklahoma as follows:

a. that the United States/State of Oklahoma be awarded damages in the amount of three times the damages sustained by the United States/State of Oklahoma because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Oklahoma and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Oklahoma Medicaid False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Oklahoma Medicaid False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXIX:
Violation of State Law: Rhode Island State False Claims Act

304. Relator, on behalf of herself and the State of Rhode Island, incorporates by reference paragraphs 1 through 303 as if set forth fully here.

305. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

306. Medicaid is jointly funded by the federal and state governments.

307. Defendants submitted or caused to be submitted claims to the Rhode Island Medicaid system and/or other government-funded system for payment or approval.

308. Pursuant to the Rhode Island State False Claims Act, Defendants are liable to the United States/State of Rhode Island for three times the amount of damages that the United States/State of Rhode Island sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Rhode Island as follows:

a. that the United States/State of Rhode Island be awarded damages in the amount of three times the damages sustained by the United States/State of Rhode Island because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Rhode Island and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Rhode Island State False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Rhode Island State False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXX:
Violation of State Law: Tennessee Medicaid False Claims Act and False Claims Act

309. Relator, on behalf of herself and the State of Tennessee, incorporates by reference paragraphs 1 through 308 as if set forth fully here.

310. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

311. Medicaid is jointly funded by the federal and state governments.

312. Defendants submitted or caused to be submitted claims to the Tennessee Medicaid system and/or other government-funded system for payment or approval.

313. Pursuant to the Tennessee Medicaid False Claims Act, codified at Tenn. Code Ann., § 71-5-181, *et seq.*, and/or the Tennessee False Claims Act, codified atTenn. Code Ann., § 4-18-101, *et seq.*, Defendants are liable to the United States/State of Tennessee for three times the amount of damages that the United States/State of Tennessee sustained, costs of the action and a penalty of not less than $5,500 and not more than $25,500 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws. The amount in controversy exceeds $500.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Tennessee as follows:

a. that the United States/State of Tennessee be awarded damages in the amount of three times the damages sustained by the United States/State of Tennessee because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $25,500 be imposed for each and every false claim that Defendants presented to the United States/State of Tennessee and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Tennessee Medicaid False Claims Act and/or the Tennessee False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Tennessee Medicaid False Claims Act and/or the Tennessee False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXXI:
Violation of State Law: Texas Medicaid Fraud Prevention Act

314. Relator, on behalf of herself and the State of Texas, incorporates by reference paragraphs 1 through 313 as if set forth fully here.

315. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

316. Medicaid is jointly funded by the federal and state governments.

317. Defendants submitted or caused to be submitted claims to the Texas Medicaid system and/or other government-funded system for payment or approval.

318. Pursuant to the Texas Medicaid Fraud Prevention Act, codified at Tex. Hum. Res. Code, § 36.001, *et seq.*, Defendants are liable to the United States/State of Texas for two times the amount of damages that the United States/State of Texas sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Texas as follows:

a. that the United States/State of Texas be awarded damages in the amount of two times the damages sustained by the United States/State of Texas because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Texas and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Texas Medicaid Fraud Prevention Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Texas Medicaid Fraud Prevention Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXXII:
Violation of State Law: Utah False Claims Act

319. Relator, on behalf of herself and the State of Utah, incorporates by reference paragraphs 1 through 318 as if set forth fully here.

320. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

321. Medicaid is jointly funded by the federal and state governments.

322. Defendants submitted or caused to be submitted claims to the Utah Medicaid system and/or other government-funded system for payment or approval.

323. Pursuant to the Utah False Claims Act, Utah Code Annotated, Title 26, Chapter 20, Defendants are liable to the United States/State of Utah for full restitution, three times the amount of damages that the United States/State of Utah sustained, costs of the action and a penalty of not less than $2,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Utah as follows:

a. that the United States/State of Utah be awarded damages in the amount of three times the damages sustained by the United States/State of Utah because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $2,000 be imposed for each and every false claim that Defendants presented to the United States/State of Utah and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Utah False Claims Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Utah False Claims Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXXIII:
Violation of State Law: Virginia Fraud Against Taxpayers Act

324. Relator, on behalf of herself and the State of Virginia, incorporates by reference paragraphs 1 through 323 as if set forth fully here.

325. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

326. Medicaid is jointly funded by the federal and state governments.

327. Defendants submitted or caused to be submitted claims to the Virginia Medicaid system and/or other government-funded system for payment or approval.

328. Pursuant to the Virginia Fraud Against Taxpayers Act, codified at Vir. Stat. Ann., § 8.01-216, *et seq.*, Defendants are liable to the United States/State of Virginia for three times the amount of damages that the United States/State of Virginia sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Virginia as follows:

a. that the United States/State of Virginia be awarded damages in the amount of three times the damages sustained by the United States/State of Virginia because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Virginia and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Virginia Fraud Against Taxpayers Act for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Virginia Fraud Against Taxpayers Act; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXXIV:
Violation of State Law: Wisconsin False Claims for Medical Assistance Law

329. Relator, on behalf of herself and the State of Wisconsin, incorporates by reference paragraphs 1 through 328 as if set forth fully here.

330. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within

such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

331. Medicaid is jointly funded by the federal and state governments.

332. Defendants submitted or caused to be submitted claims to the Wisconsin Medicaid system and/or other government-funded system for payment or approval.

333. Pursuant to the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931, *et seq.*, Defendants are liable to the United States/State of Wisconsin for three times the amount of damages that the United States/State of Wisconsin sustained, costs of the action and a penalty of not less than $5,500 and not more than $11,000 for each false claim. The highest possible penalties are appropriate in this case in light of the Defendants' actual knowledge. The highest possible penalties are also appropriate in this case to send a message to Defendants' industry that they must abide by federal and state laws.

WHEREFORE, Relator respectfully request that the Court enter judgment against Defendants and in favor of the United States/State of Wisconsin as follows:

a. that the United States/State of Wisconsin be awarded damages in the amount of three times the damages sustained by the United States/State of Wisconsin because of the false claims alleged within this Second Amended Complaint;

b. that civil penalties of $11,000 be imposed for each and every false claim that Defendants presented to the United States/State of Wisconsin and/or its grantees;

c. that pre- and post-judgment interest be awarded along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing and pressing this case;

d. that the Court grant permanent injunctive relief to prevent any recurrence of the Wisconsin False Claims for Medical Assistance Law for which redress is sought in this Second Amended Complaint;

e. that the Relator be awarded the maximum amount allowed to her pursuant to the Wisconsin False Claims for Medical Assistance Law; and

f. that this Court award such other and further relief as it deems proper.

COUNT XXXV:
Common Fund

334. Relator, on behalf of herself, incorporates by reference paragraphs 1 through 333 as if set forth fully here.

335. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

336. Medicaid is jointly funded by the federal and state governments.

337. Defendants submitted or caused to be submitted claims to state Medicaid programs in all fifty states and the District of Columbia.

338. Relator's efforts have or will create, discover, increase or preserve a fund to which others also have a claim.

339. Relator is entitled to recover from the fund.

340. States will receive a benefit from the common fund that Relator has or will create.

341. If any state that does not provide for a statutory fee to Relator is allowed to obtain the benefit of this case without contributing to its costs, that state without a statutory fee to Relator will be unjustly enriched at the expense of Relator.

342. Any state that does not provide for a statutory fee to Relator and that benefits from the fund will be easily identifiable.

WHEREFORE, Relator respectfully requests that the Court enter judgment in her favor for all relief as the Court deems proper in law and equity including the costs of the litigation and reasonable attorneys' fees.

COUNT XXXVI:
Common Law *Qui Tam*

343. Relator, on behalf of herself, incorporates by reference paragraphs 1 through 342 as if set forth fully here.

344. Pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Relator's state law claims because they are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

345. Medicaid is jointly funded by the federal and state governments.

346. Defendants submitted or caused to be submitted claims to the state Medicaid programs in all fifty states and the District of Columbia.

347. Relator's efforts have or will create, discover, increase or preserve a fund in which the state governments will share.

348. The term *qui tam* is Latin for the phrase "he who brings an action on behalf of the king as well as for himself."

349. Pursuant to the common law of *qui tam*, Relator is entitled to recover a portion of the fund that is shared by all fifty states and the District of Columbia (including states that do not provide a statutory fee to Relator) as a result of Relator's efforts.

WHEREFORE, Relator respectfully requests that the Court enter judgment in her favor for a portion of the fund in which the governmental entities will share, costs of the litigation, including reasonable attorneys' fees, and all other and further relief as the Court deems proper in law and equity.

Demand for Jury Trial/Designation of Place of Trial

Relator, on behalf of the United States and the States named herein, and on behalf of herself, hereby demands a trial by jury on all counts and allegations of wrongful conduct alleged in this Second Amended Complaint in the United States District Court for the District of Kansas, Kansas City, Kansas.

Respectfully submitted,

/s/ Carrie M. Brous
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ATTORNEYS FOR RELATOR

Certificate of Service

I hereby certify that a copy of the foregoing filed under seal with the Court is being served via e-mail to:

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(Pursuant to 31 USC § 3732(c) (as amended by the Fraud Enforcement and Recovery Act of 2009 (123 Stat 1617 (May 20, 2009)) and the state statutes listed in Counts III-XXXIV)

/s/ Carrie M. Brous
Attorney for Relator