UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA;

THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, and WISCONSIN;

THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and

THE DISTRICT OF COLUMBIA,

ex rel. [UNDER SEAL],

Plaintiffs,

v.

AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN SPECIALTY GROUP; INTERNATIONAL ONCOLOGY NETWORK; ONCOLOGY SUPPLY COMPANY; and MEDICAL INITIATIVES, INC.,

Defendants.

CIVIL ACTION NO.
CV-10-4856

(Gershon, J.)
(Go, M.J.)

FILED *IN CAMERA*
and UNDER SEAL

JURY TRIAL DEMANDED

FIRST AMENDED FALSE CLAIMS ACT *QUI TAM* COMPLAINT

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NATURE OF THE ACTION

1. This is an action brought on behalf of the United States of America by Plaintiff Michael Mullen (hereafter referred to as "Relator") against Defendants pursuant to the *Qui Tam* provisions of the civil False Claims Act, 31 U.S.C. §§ 3729-3733 ("Federal FCA" or "FCA"), and on behalf of the above-named states under their respective State False Claims Acts ("State FCAs") (together, referred to herein as "*Qui Tam* Action"). Pursuant to 31 U.S.C. § 3730(b)(2), and comparable provisions in the State FCAs, this *Qui Tam* Action is brought *in camera* and under seal. Relator also alleges personal claims against Defendants for retaliation against his having engaged in statutorily protected conduct, in violation of subsection (h) of the Federal FCA, and in violation of the civil Texas FCA, Hum. Res. Code § 36.001 *et seq.* (2005), and Texas common law.

2. Relator is a former Chief Operating Officer ("COO") (and before that Chief Financial Officer ("CFO")) of Defendant AmerisourceBergen Specialty Group ("ABSG"), an operating segment of Defendant AmerisourceBergen Corporation ("ABC"), and a former member of the ABC Corporate Ethics Committee. Mr. Mullen had been with ABSG for almost seven years when he was terminated from active employment without warning on April 8, 2010, after presenting his concerns about various aspects of ABSG's business practices to, among others, his predecessor at ABSG, Steven H. Collis (who is now President and COO of ABC) and to R. David Yost, Chief Executive Officer ("CEO") and a board member of ABC.

3. Defendant ABC is the only major drug wholesaler who owns an oncology distributor (Defendant Oncology Supply Company ("OSC")), an oncology group purchasing organization ("GPO") (Defendant International Oncology Network ("ION")), and a purported oncology pharmacy (Defendant Medical Initiatives, Inc. ("MII")).

4. Defendants ION, OSC, and MII are businesses that are owned by Defendant ABC and operated by Defendant ABSG. Defendant OSC is the largest distributor to community oncologists (*i.e.*, physicians as opposed to hospitals) in the country. ION is the largest oncology GPO in the country. MII operates what purports to be a large "pharmacy" at OSC's location in Dothan, Alabama (under one or more pharmacy license(s) in the name of MII and/or Oncology Supply Pharmacy Services and/or OS Pharmacy).

5. The community oncology channel is large, growing, and accounts for a material amount of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, (hereinafter "Medicare") Part B drug expenditures. The community oncology channel, in total, represents approximately $14 to $18 billion of activity annually of which ABC owns about 45%-55% market share. Of that total, Relator estimates that at least 50% is funded through reimbursements from Government Health Care Programs such as Medicare and Medicaid.

6. The allegations of this First Amended Complaint arise from Relator's first-hand knowledge of the unlawful practices of Defendants with respect to several fraudulent schemes involving large volumes of oncology drugs sold by Defendants to community oncologists on behalf of drug manufacturers and billed by the providers to Medicare, Medicaid, and other government funded health care programs.

7. First, Relator has first-hand knowledge that Defendant ION does not function as a true, legitimate GPO. In essence, drug companies paid what were purported to be administrative or service fees to ION in connection with ION's services as a GPO. These administrative fees, however, were not paid by the manufacturers to ION in return for fair market value *bona fide* services, but rather were a way for drug companies (and ION and OSC) to pass-through price discounts to medical providers. In addition, ION and OSC provided numerous types of free

services to providers and did not function as a true GPO should. These administrative fees did not qualify for the Medicare Medicaid Patient Protection Act (also known as the Anti-Kickback Statute ("AKS")) safe-harbor for GPOs, and constituted kickbacks in violation of the AKS, 42 U.S.C. § 1320a-7b(b), and, accordingly, the FCA. Moreover, Relator knows or has a good faith basis to believe that these discounts, as well as a large portion of the administrative fees (*i.e.*, the portion that did not represent fair market value for a *bona fide*, itemized service actually performed), were not included in the calculation of the Average Sales Price ("ASP") for the drugs in question, thereby artificially inflating the ASP and resulting in a higher profit to the medical provider than the ASP plus 6% set by Medicare effective January 1, 2005 (and other prices set under Government Health Care Programs including, without limitation, Average Wholesale Price ("AWP"), Wholesale Acquisition Cost, Best Price, and Average Manufacturer Price in effect before and after January 1, 2005). This inflated profit was another form of kickback in violation of the AKS and, accordingly, the FCA, and the misstatement of the ASP (and other prices) it gives rise to, is a separate violation of the FCA.

8. Second, the so-called MII "pharmacy" is a pharmacy in name only. In actuality, MII is a drug repackager and manufacturer that is not registered with the Food and Drug Administration ("FDA"). MII, in connection with ION and OSC, engaged in an illegal "overfill" laundering scheme designed to pass illegal kickbacks to medical providers and which also had the effect of over-reporting the ASP (and other prices) of the drug. Each vial of an injectable drug contains a certain amount of drug above the labeled fill volume. This amount, known as overfill, is free to the purchaser and is typically included to ensure that the medical providers can withdraw and administer the full labeled fill volume (*i.e.*, dose) to their patients. OSC purchased vials of injectable drugs from other drug manufacturers and sold these vials to MII. MII then

used sophisticated centrifuge and vacuum technology to extract all of the product from these vials, including the free overfill amounts; and manufactured pre-filled syringes with this product, including the free overfill. These pre-filled syringes were then sold back to OSC, for sale to providers. By doing this, Defendants were able to create free doses of the drug from the overfill contained in the drug vials. These pre-filled syringes were sold to medical providers at a much steeper discount than was offered on the equivalent vials from which the syringes were manufactured. This scheme allowed Defendants to make a greater profit, to pass-through further illegal price concessions to medical providers, and to artificially inflate the ASP calculations (and other prices set under Government Health Care Programs including, without limitation, AWP, Wholesale Acquisition Cost, Best Price, and Average Manufacturer Price), upon which Government Health Care Programs reimburse providers. Indeed, under federal regulations, all manufacturers and repackagers, such as MII, are required to report ASP data, reflecting the ASP by National Drug Code ("NDC") for each drug manufactured or repackaged, on a quarterly basis to the Department of Health and Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS"). *See* 42 C.F.R. § 414.804(a)(5). MII never did so, and therefore the price effect of its illegal overfill laundering scheme was never reflected in the drugs' ASP. This inflated ASP was another form of kickback in violation of the AKS and accordingly, the FCA, and the misstatement of the ASP (and other prices) gives rise to a separate violation of the FCA.

9. Third, because MII is an unlicensed manufacturer and repackager, it, and its corporate parent (who is fully aware of this activity) are in violation of a host of state and federal laws, including Alabama's laws governing the operating authority of local pharmacies, and at least equally significant, the federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDA's regulation over drug manufacturers and repackagers pursuant to the

FDCA is plenary. As set forth more fully below, MII has not only been operating intentionally below the FDA's radar screen, but it has violated any number of FDA mandated protocols designed to protect against contamination, product mix-ups, mis-identification, mis-labeling, deficient inventory control, deficient lot number identification, etc. The manipulation of sterile drug products – as they are removed from sterile vials and placed in pre-filled syringes (as in MII's operation), is an area of particular concern to the FDA. MII and its corporate parent have endangered public health through this unlicensed, unregulated repackaging operation, by reintroducing into commerce misbranded and adulterated drug products repackaged by MII's facility in Alabama – including potentially dangerous biologic drugs used to treat cancer patients.

10. As a direct, proximate, and foreseeable result of Defendants' fraudulent course of conduct set forth herein and conducted on a national scale, Defendants knowingly caused the submission of hundreds of thousands of false or fraudulent statements, certifications, and claims to Government Health Insurance Programs for the reimbursement of oncology drugs sold through ION and OSC from at least May 2003 through at least April 2010, when Relator was actively employed by Defendant ABSG.

11. Moreover, the practices complained of herein are continuing. As detailed below, Defendants' actions and omissions have caused many years of improper and illegal billings to Government Health Care Programs, the United States, and the states.

12. Defendants' fraudulent conduct has had a dramatic impact on Medicare, Medicaid and federal and state government fiscs.

13. By their actions, Defendants have violated several laws, including without limitation, the FCA, the AKS, and the FDCA.

14. In addition to the *Qui Tam* Action claims described above, Relator also brings claims of retaliation against Defendant ABSG, in violation of the anti-retaliation provisions of the Federal FCA and Texas state law.

15. Information about Defendants' illegal conduct is detailed further in the paragraphs below.

JURISDICTION AND VENUE

16. This Court has jurisdiction over this action under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has jurisdiction over Relator's private cause of action for retaliation, under 31 U.S.C. § 3730(h). This Court has supplemental jurisdiction over the State FCA claims, as well as over Relator's private causes of action under Texas statutory and common law, pursuant to 28 U.S.C. § 1367.

17. Under 31 U.S.C. § 3730(e)(4)(A), there has been no statutorily relevant public disclosure of substantially the same "allegations or transactions" alleged in this First Amended Complaint. Even to the extent there has been any such public disclosure, Relator meets the definition of an original source, as that term is defined under 31 U.S.C. § 3730(e)(4)(B). Specifically, Relator voluntarily disclosed to the government the information upon which allegations or transactions at issue in this complaint are based prior to any purported public disclosure under 31 U.S.C. § 3730(e)(4)(A). Alternatively, Relator has knowledge that is independent of and materially adds to any purported publicly disclosed allegations or transactions, this First Amended Complaint is based on Relator's direct and independent knowledge as an employee (now former) of Defendant ABSG and Relator voluntarily provided the information to the government before this complaint was filed. Relator therefore qualifies as

an "original source" of the allegations in this First Amended Complaint such that the so-called public disclosure bar set forth at 31 U.S.C. § 3730(e)(4) is inapplicable.

18. Venue is appropriate as to Defendants in that Defendants can be found, reside, and/or transact business in this judicial district, and/or acts proscribed by 31 U.S.C. § 3729 have been committed by Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a).

THE PARTIES

19. The real party in interest to the FCA *Qui Tam* Action claims herein is the sovereign government of the United States of America and the sovereign governments of the named State Plaintiffs. At this time, Relator is pursuing his cause of action on behalf of the named Plaintiffs the United States and the states on the FCA *Qui Tam* Action claims set forth herein pursuant to 31 U.S.C. § 3730(c)(3) and comparable provisions of State FCAs. Relator is also pursuing on his own behalf claims that Defendant ABSG retaliated against him in violation of federal and state law.

20. Relator Michael Mullen is a citizen of the United States of America. He is a resident of the State of Texas, and a former employee of Defendant ABSG. He brings this *Qui Tam* Action based upon direct, independent, and unique information obtained during the period of his employment at ABSG from May 2003 to April 2010.

21. Defendant AmerisourceBergen Specialty Group is the specialty pharmaceutical business arm of Defendant AmerisourceBergen Corporation. ABSG is the largest specialty pharmaceutical services provider in the United States with approximately $16 billion in annual revenues in its fiscal year ended September 2010. "Specialty pharmaceuticals" are biological drugs that are expensive and difficult to handle. Among other things, ABSG distributes specialty

pharmaceuticals, and is hired by drug manufacturers to provide services related to reimbursement, consulting, and logistics related to specialty pharmaceuticals. ABSG is headquartered at 3101 Gaylord Parkway, Frisco, Texas 75034. ABC is the parent corporation of ABSG, is a Delaware corporation, and is headquartered at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. ABC does business through numerous subsidiaries or operating divisions including Defendants ABSG, OSC, ION, and MII. ABC and its subsidiaries/divisions operate and conduct business throughout the United States, Puerto Rico, and Canada. ABC had approximately $71 billion in annual revenues in 2009 and advertises on its website that it "handle[s] about 20% of all of the pharmaceuticals sold and distributed throughout the country." AmerisourceBergen, Who We Are, *available at* http://www.amerisourcebergen.com/abc/Who_We_Are/index.jsp.

22. Defendant International Oncology Network, formerly known as the "Indian Oncology Network," was formed in the 1990s and operated as one of several d/b/a companies of an entity known as International Physicians Network ("IPN") (other d/b/a companies used by IPN include International Nephrology Network ("INN"), International Urology Network, and International Rheumatology Network). ABC/ABSG acquired ION in or about 2001. ION is purportedly a GPO that focuses on oncology practices and physicians. Its principal place of business is 3101 Gaylord Parkway, Frisco, Texas 75034-8655. ION is the largest oncology GPO in the country and does business throughout the United States.

23. Defendant Oncology Supply Company is a pharmaceutical distributor operated by ABSG, whose ultimate parent is ABC. OSC's principal place of business is 2801 Horace Shepard Drive, Dothan, Alabama 36303-1038. OSC is the largest pharmaceutical distributor to community oncologists in the country, distributes drugs throughout the United States, and is the

preferred distributor for ION. OSC was acquired by Bergen Brunswig (a predecessor to ABC) in 1996.

24. Defendant MII purports to be an oncology "pharmacy" and is a subsidiary of OSC. MII's principal place of business is 2801 Horace Shepard Drive, Dothan, Alabama 36303-1038. MII operates a large repackaging facility at OSC's location in Dothan, Alabama (under one or more pharmacy license(s) in the name of MII and/or Oncology Supply Pharmacy Services and/or OS Pharmacy). MII is not registered with the FDA as a repackager or manufacturer of drugs or drug products, even though repackaging and manufacturing of pre-filled syringes from vials purchased from manufacturers constitutes the entire scope of its activities. Rather, MII is licensed only by the State of Alabama, as a pharmacy, even though its activities far exceed the scale and scope of traditional pharmacies.

FEDERAL AND STATE LAWS AND REGULATIONS

A. The Anti-Kickback Statute of the United States and the States

25. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the medicare and medicaid programs." Social Security Amendments of 1972, H.R. Rep. No. 92-231, at 104 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

26. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendments of 1972, H.R. Conf. No. 92-603, § 241(b), (c), *reprinted in* 1972 U.S.C.C.A.N. 5370; 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." Medicare-Medicaid Antifraud and Abuse Amendments, H.R. Rep. No. 95-393(II), at 7 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047.[1]

27. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, H.R. Conf. Rep. No. 95-673, at 3 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3113, 3115; Medicare and Medicaid Patient and Program Protection Act of 1987, S.R. No. 100-109, at 26, *reprinted in* 1987 U.S.C.C.A.N. 682, 707-08.

28. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in

[1] Through the amendments Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept. 30, 1997) (statement of Sen. Talmadge).

part by a federal health care program, which includes any state health program or health program funded in part by the federal government. *See* 42 U.S.C. § 1320a-7b(b), (f).

29. The statute provides, in pertinent part:

> (b) Illegal remunerations
>
> * * *
>
> (2) 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 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 $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

30. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

31. In 1991, the HHS Office of Inspector General ("HHS OIG") promulgated regulations under the AKS. *See* Medicare and State Health Care Programs: Fraud & Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) ("HHS OIG Anti-Kickback Provisions").

32. Concern about improper drug marketing practices further prompted the HHS OIG to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback Statute. *See* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994) (Special Fraud Alert: Prescription Drug Marketing Schemes).

33. Then, on June 11, 2001, the HHS OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry. *See* Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry, 66 Fed. Reg. 31,246 (June 11, 2001). The HHS OIG's resulting draft guidance was published for notice and comment in October 2002, *see* Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057 (Oct. 3, 2002), and in May 2003, the HHS OIG published further guidance on marketing practices which may constitute kickbacks and other illegal remuneration affecting federal health care programs known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23,731 (May 5, 2003) (the "OIG Guidelines").

34. Among other things, the guidelines caution against engaging in "marketing the spread": "[t]o the extent that a manufacturer controls the 'spread,' it controls a customer's profit." It further observes that "[t]he conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." OIG Guidelines, 68 Fed. Reg. at 23,736-37.

35. The "spread" refers to the difference in value between what a provider pays for a drug and the reimbursement that the provider receives (usually from government or private health insurance) for a drug to be administered to a beneficiary. The greater the difference

between provider cost and program reimbursement, the greater the "spread" – and the greater the provider profit.

36. In 2003 when the OIG Guidance was published, under the Medicare Program, and other federal and state health care programs, prescription drug reimbursement amounts generally used the AWP as a benchmark price to determine reimbursement. The AWP for a prescription drug is a self-reported price, *i.e.*, it is not independently and objectively determined. Rather, manufacturers provide AWP data to publications such as First Data Bank, which publish the information without scrutiny.

37. After the OIG Guidelines were issued, CMS replaced AWP with ASP plus 6%, effective January 1, 2005, as the basis for Medicare drug reimbursement. State Medicaid Programs use varying reimbursement methodologies, including AWP, ASP, Best Price, Average Manufacturer Price, and Wholesale Acquisition Cost. Regardless of what methodology is used, marketing the spread constitutes illegal remuneration and violates the AKS.

38. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment or other remuneration to a physician or other person which has as one of its purposes the inducement to purchase, administer and/or write prescriptions for one manufacturer's pharmaceutical products or the inducement to influence or recommend the prescribing of the product. The AKS remuneration provision is very broad in plain language and in purpose: it prohibits "offer[ing] or pay[ing] *any* remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(2)(B) (emphasis added). The AKS further defines "remuneration" to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6). Underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56

Fed. Reg. at 35,958, broadly define the term "remuneration" as "anything of value in any form . . . whatsoever." *See also* OIG Guidelines, 68 Fed. Reg. at 23,734 (AKS addresses the offer or payment of "anything of value").

39. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid or other Government Health Care Program reimbursement is sought.

40. The most basic requirement for reimbursement eligibility under Medicare is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.* Medicaid and other Government Health Care Programs have similar provisions. Under 42 U.S.C. § 1395y(a)(1)(A), "no[n]payment may be made [under the Medicare statute] for any expenses incurred for items or services [] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

41. Federal law makes clear that violation of the Anti-Kickback Statute can support FCA liability. For example, the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 119 (2010) ("PPACA"), which became law on March 23, 2010, provides: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the FCA]." In other words, pursuant

to the PPACA, claims for items or services billed to government-funded healthcare programs (including Medicare) "resulting from" a violation of the anti-kickback statute are, without question, "false or fraudulent claims" under the FCA.

42. Under federal law, proof that a defendant knew of and specifically intended to violate the AKS is not required; rather, proof that the defendant intended to perform the actions that violated the AKS gives rise to a violation. *See also* PPACA § 6402(f)(2) ("a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation").

43. At all times relevant to this First Amended Complaint, compliance with the AKS has been a condition to participation for a health care provider under Medicare and other Government Health Care Programs. Moreover, compliance with the AKS is a *condition of payment* for claims made to Medicare and other Government Health Care Programs for reimbursement. A violation of the Anti-Kickback Statute, *see supra*, is material to the government's decision to pay, and a violation of the Anti-Kickback Statute renders resulting claims to Medicare or other Government Health Care Programs false or fraudulent in violation of the FCA.

44. The AKS covers all Government Health Care Programs, including Medicare and Medicaid. In addition, some states have their own versions of an AKS, including without limitation, the States of California, Georgia, Illinois, Massachusetts, Michigan, New Mexico, New York, and Virginia. There is a safe harbor for discounts in the AKS that protects "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately

reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A).

45. The requirements of the safe harbor are further enumerated at 42 C.F.R. § 1001.952(h). Although there is a safe harbor to the AKS for valid discounts, that does not include "supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology." *See* 42 C.F.R. § 1001.952(h)(5)(ii); Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999) (Final Rule).

B. <u>The Federal and State FCAs</u>

46. The FCA, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999. *See* 28 C.F.R. § 85.3.

47. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999. *See* 28 C.F.R. § 85.3.

48. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999. *See* 28 C.F.R. § 85.3.

49. The FCA, 31 U.S.C. § 3729(a)(1)(G), makes any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government liable for three times the amount of damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999. *See* 28 C.F.R. § 85.3.

50. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. *See* 31 U.S.C. § 3729(b)(2).

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

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

53. The FCA also contains an anti-retaliation provision protecting employees, contractors, and agents from improper adverse action by a defendant. Subsection (h) of 31 U.S.C. § 3730 provides as follows: "Any employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop [one] or more violations of this subchapter." Subsection (h) goes on to specify that an employee who successfully sues under this anti-retaliation provision shall be entitled to 1) reinstatement, 2) two times back pay plus interest, 3) compensation for any special damages, and 4) costs and reasonable attorney's fees.

54. The civil Texas Medicaid Fraud Prevention Act (Hum. Res. Code § 36.115) contains a parallel anti-retaliation provision, which contains liability and relief language that is virtually identical to the federal FCA.

55. As set forth below, several states have passed FCA legislation, which in most instances closely tracks the Federal FCA: California FCA, Cal. Gov't Code § 12650 *et seq.*, Colorado Medicaid FCA, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*, Connecticut FCA, Conn. Gen. Stat. § 17b-301 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia FCA, D.C. Code § 2-308.03 *et seq.*, Florida FCA, Fla. Stat. § 68.081 *et seq.*, Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*, Hawaii FCA, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois False Claims Whistleblower Reward and

Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*, Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*, Maryland False Health Claims Act of 2010, Md. Code Health-Gen. § 2-601 *et seq.*, Massachusetts FCA, Mass. Gen. Laws Ch.12, § 5A *et seq.*, Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.601 *et seq.*, Minnesota FCA, Minn. Stat. § 15C.01 *et seq.*, Nevada FCA, Nev. Rev. Stat. § 357.010 *et seq.*, New Hampshire FCA, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*, New Jersey FCA, N.J. Stat. Ann. § 2A:32C-1 *et seq.*, New Mexico Medicaid FCA, N.M. Stat. Ann. § 27-14-1 *et seq.*, New York FCA, N.Y. State Fin. Law § 187 *et seq.*, North Carolina FCA, N.C. Gen. Stat. § 1-605 *et seq.*, Oklahoma Medicaid FCA, Okla. Stat. Ann. tit. 63 § 5053 *et seq.*, Rhode Island State FCA, R.I. Gen. Laws § 9-1.1-1 *et seq.*, Tennessee FCA, Tenn. Code Ann. § 4-18-101 *et seq.*, Texas FCA, Tex. Hum. Res. Code § 32.001 *et seq.*, Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*, and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. Ann. § 20.931 *et seq*. These State FCAs apply, *inter alia*, to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *Qui Tam* provisions governing, *inter alia*, a relator's right to claim a share of the state's recovery.

C. Group Purchasing Organizations

56. GPOs are buying consortiums or associations of hospitals, clinics, doctors, and healthcare organizations that are designed to leverage the aggregate purchasing power of members and thereby increase their ability to negotiate contract terms with various suppliers of drugs, medical devices, and other goods and services. GPOs negotiate such acquisitions, but do not typically purchase anything from the suppliers. Once a contract is in place, the member

hospitals and healthcare organizations can make purchases under it. *See, e.g.*, HHS OIG Report, *Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members* No. A-05-03-00074 (Jan. 19, 2005), *available at* http://oig.hhs.gov/oas/reports/region5/50300074.pdf.

57. The term "group purchasing organization" is defined at 21 C.F.R. § 203.3 as follows:

> § 203.3 Definitions.
>
> (o) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

(Emphasis added.) GPOs act as agents for their members, but they may be compensated through "administrative" or "service" fees from the vendors or suppliers. These fees are paid by the vendors or suppliers to the GPO in exchange for administrative services and the ability to sell through the GPO to its members. *See* OIG Report, *supra*. Typically, the fees are calculated as a small percentage, generally less than 3%, of the revenue generated under the GPO contract. *See id.*

58. The Anti-Kickback Statute provides certain exemptions (known as "safe harbors") to exclude certain conduct from its ambit, *as long as* the involved parties have complied with all the conditions of the safe harbor. One such safe harbor involves GPO administrative fees.

59. Regulations promulgated by the HHS OIG limit this "safe harbor" by imposing standards for the written agreement between the GPO and its members. *See* 42 C.F.R. § 1001.952(j). A GPO may invoke the "safe harbor" if:

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following –

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term group purchasing organization (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

Id.

60. Parties to a GPO arrangement cannot obtain safe harbor protection by entering into a contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but that does not reflect the actual arrangement between the parties. *See generally* 42 C.F.R. § 414.802 (fees must be "bona fide" to be excluded from ASP calculations).

61. Administrative or service fees charged by GPOs and paid to them by vendors are also material to Medicare's calculation of the ASP at which a covered drug is reimbursed.

62. Beginning on January 1, 2005, Medicare Part B reimbursement for injectable drugs in the physician clinic setting was based on a new formula calculated as "average selling

price" ("ASP") plus six percent – *i.e.*, ASP + 6%. The regulations governing ASP were promulgated in 2004. *See* 42 C.F.R. § 414.800. In calculating ASP, a manufacturer must deduct "price concessions," but "*bona fide* services fees" are not considered a concession. 42 C.F.R. § 414.804(a)(2) (emphasis added).

> Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 C.F.R. § 414.802.

63. All drug manufacturers and repackagers are required to submit ASP data on a quarterly basis indicating the ASP for each NDC it sells and the units of each NDC sold by that manufacturer or repackager. *See* 42 C.F.R. § 414.804; CMS Question and Answers, *available at* https://questions.cms.hhs.gov/app/answers/detail/a_id/3307/related/1.

64. When a manufacturer or repackager submits its ASP-required information to CMS (which it is required to do on a quarterly basis), the manufacturer's CEO, CFO, or Authorizing Official must certify that "the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes." CMS, Average Sales Price Data, Add. B, *available at* https://www.cms.gov/McrPartBDrugAvgSalesPrice/Downloads/aspdata_addendumb.pdf; *see also* 42 C.F.R. § 414.904. Certain State Medicaid programs also base reimbursement for covered drugs on ASP.

65. Administrative or service fees charged by GPOs and paid to them by manufacturers/vendors are also material to Government Health Care Programs' calculation of the prices at which a covered drug is or has been reimbursed during the time period relevant to this First Amended Complaint, including without limitation AWP, AMP, WAC, and BP.

D. The FDA's Regulation of Drugs: the Distinction, Under State and Federal Law, Between Pharmacies and Drug Repackager and Manufacturers

66. Under both federal and state law, there exists an important distinction between pharmacies and drug manufacturers or repackagers. Traditional pharmacies, which typically dispense drug products in fulfillment of patient prescriptions written by physicians, are exempt from many of the legal and operating requirements the FDA imposes on drug manufacturers and repackagers pursuant to the FDCA and other statutes, leaving regulation of traditional pharmacies principally to the states. However, because pharmacies often engage in activities such as compounding, both federal and state authorities have issued detailed guidance on the issue of what sorts of activities will cause a pharmacy to be considered a drug manufacturer or repackager subject to FDA regulation and enforcement jurisdiction. The distinction is a matter of great importance to the FDA because pharmacies acting as manufacturers or repackagers could potentially escape the FDA's oversight on such important regulatory requirements as "product mix-up, loss of product identity, contamination and cross-contamination, lack of stability data to support expiration dates, and the lack of adequate control systems," FDA Program Manual, Chapter 56; issues which bear directly on public health and safety.

67. If an enterprise holding itself out as a pharmacy engages in the activity of a drug manufacturer or repackager, both the FDA and the states have made clear that such a "pharmacy" will be subject to the same rules as manufacturers or repackagers. For example, the FDA has issued specific guidance that:

> Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.
>
> *However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action.*

FDA, Compliance Policy Guides Manual, *Compliance Policy Guidance for FDA Staff and Industry* § 460.200 (May 29, 20020) ("FDA Compliance Policy Guide") (emphasis added), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm.

68. Defendants are well aware of these distinctions and rules. Defendant ABC has, since 2003, owned a repackaging enterprise, Anderson Packaging, Inc. ("Anderson"), located in Rockford, Illinois, where drugs purchased in bulk from manufacturers are repackaged into kits or other smaller containers for resale. Defendant ABC has its own labeler codes for purpose of the NDC tracking system, as is required. Thus, in the course of its routine review and supervision of its operating subsidiaries, Defendant ABC knew, or should have known, of the applicable rules of the FDA governing repackagers of drug products.

69. Congress defined the term "manufacture" in Section 510 of the FDCA, 21 U.S.C. § 360(a)(1), to include: "repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer." *See also* 42 U.S.C. § 1396r-8(k)(5):

> The term "manufacturer" means any entity which is engaged in –

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

70. Similarly, the State of Alabama (the state in which Defendant MII operates) has defined "manufacturing" in pertinent part as follows:

> The production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance or substances or labeling or relabeling of its container and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by a pharmacy, practitioner, or other person. The distribution of inordinate amounts of compounded products without a prescriber / patient/ pharmacist relationship is considered manufacturing.

Ala. Code § 34-23-150(5).

71. Thus, under both federal and Alabama law, when a purported "pharmacy" exceeds the scope of traditional pharmacy practice by engaging in repackaging activities on a large commercial scale, such a "pharmacy" is subject to the full panoply of legal and regulatory requirements applicable to drug manufacturers and repackagers. These include, without limitation, the duty to register as a drug manufacturer or repackager with the FDA, and to avoid misbranding drug products, or distributing adulterated drug products, in violation of the FDCA. Furthermore, as set forth above, the purported pharmacy must submit ASP Data, reflecting the ASP by NDC for each drug manufactured or repackaged by that purported pharmacy, on a quarterly basis to CMS. *See* 42 C.F.R. § 414.804(a)(5).

72. The FDA has made clear that it views the distinction between pharmacies and manufactures or repackagers as a matter of high priority:

> FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act. Such establishments and their activities are the focus of this guidance. ***Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies.*** For example, some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them. ***Moreover, some firms sell to physicians and patients with whom they have only a remote professional relationship. Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers.***

FDA Compliance Policy Guide § 460.200 (emphases added).

73. Drug manufacturers and repackagers are subject to civil and criminal penalties for introducing "misbranded" or "adulterated" drug products into the stream of commerce. A drug product may be misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). "Misleading" is defined by statute (21 U.S.C. § 321(n)) and 21 C.F.R. § 201.56 to include not only affirmative mis-statements but also omissions of material fact.

74. There are many types of misbranding offenses. A drug is mis-branded, for example, if it is not listed with the FDA, or "if it does not bear such symbols from the uniform system for identification of devices [and drugs, *see* 21 C.F.R. § 207.35] prescribed under Section 360(e) as the Secretary by regulation requires." Section 360(e) expressly designates that the NDC assigned by the Secretary during the drug listing process as the symbol of the uniform system of identification of drugs. In other words, one of the ways in which a drug may be misbranded is if it fails to carry an accurate NDC number, allowing the FDA and consumers to trace its origin and pedigree.

75. In addition, a drug may be "misbranded" because it is manufactured or repackaged in an establishment not duly registered under Section 510 of the FDCA (21 U.S.C. § 360). Drugs produced at an unregistered facility are *per se* misbranded, because, *inter alia*, the drugs' labeling omits material information about the facility's authority to produce the drugs in the first instance. *See* 21 U.S.C. § 352(o).

76. A drug may be "adulterated," under 21 U.S.C. § 351(a)(1)-(3), if it contains any "filthy, putrid, or decomposed substance," if it has been "prepared, packed or held under unsanitary conditions . . . ," if "the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding did not conform to or are not operated . . . in conformity with current good manufacturing practice . . . ", if the methods used in a drug's manufacture do not meet good manufacturing practices, or if the drug's container is "composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." Sale of adulterated drug products carries both civil and criminal sanctions. The prohibitions against sale and distribution of both misbranded and adulterated drugs are premised on the need to protect public health and safety.

77. One of the reasons drug manufacturers and repackagers must register with the FDA is to allow the agency the right to inspect the facilities in question to ensure that there are no misbranding or adulteration issues. *See* 21 U.S.C. § 374(a)(1)(B). The agency routinely inspects drug manufactures and repackagers (but not pharmacies) to ensure compliance with "current good manufacturing practices" or "CGMPs." The "failure to comply with any regulation set forth" regarding good manufacturing practices "in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated." 21 C.F.R. § 210.1(b). As one example, a failure to document "stability testing" to ensure that the stated expiration date

is still effective, *see id.* § 211.166, would render the product "adulterated," as would comingled, mislabeled, or mispackaged drug product. *See United States v. Richlyn Labs., Inc.*, 827 F. Supp. 1145, 1151 (E.D. Pa. 1992).

78. With respect to the manufacture of pre-filled syringes, the FDA has articulated specific CGMP guidelines, discussed in detail in the pages that follow. Failure to meet these CGMP standards renders all of the pre-filled syringes manufactured at such a facility "adulterated" within the meaning of the FDCA.

79. Finally, the FDA has made clear to the regulated industries that "a switch from liquid-filled vials . . . to prefilled syringes [as in a repackaging operation] requires submission of a supplemental new drug application (sNDA)." Brian Lane & Timothy Rhines, *Ensure Quality, Safety of Prefilled Syringes* (Pharm. Formulation & Quality Oct./Nov. 2010), *available at* http://www.pharmaquality.com/ME2/Audiences/dirmod.asp?sid=325598564E8C4B3EB736C7159241312D&nm=Browse+Articles&type=Publishing&mod=Publications%3A%3AArticle&mid=D3E3C719D8D44216836DCA4F4144BEC4&tier=4&id=DEE72FDB29DD4F72837432CC023ECEF2&AudID=5648A5C28C97462DBBDB309539B820EF; *see* FDA Warning Letter No. NWE-06-07W to New England Compounding Center, *at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm ("FDA Letter NWE-06-07W"). Repackaged drugs may not be introduced into commerce without the approval of the FDA, and the agency has made clear that the repackaging of liquid filled vials into pre-filled syringes renders the final product a "new" drug subject to FDA new drug approval requirements, *i.e.*, requiring a supplemental application. Failure to comply with these sNDA requirements is an additional ground for determining drug products to be "misbranded."

80. Government Health Insurance Programs do not pay for misbranded or adulterated products. Claims for reimbursement against Government Health Insurance Programs that are based upon the sale or administration of misbranded or adulterated drugs are "false" and "fraudulent" claims within the meaning of the Federal and State FCAs.

GOVERNMENT HEALTH INSURANCE PROGRAMS

81. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, is a health insurance program administered by the government of the United States that is funded by taxpayer revenue. Medicare is overseen by the United States Department of Health and Human Services through its CMS.

82. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services, and durable medical equipment to persons over sixty-five (65) years of age, and for certain others that qualify under the terms and conditions of the Medicare Program.

83. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with cancer and chronic kidney disease. Individuals who receive benefits under Medicare are commonly referred to as "beneficiaries."

84. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

85. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. *See* 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

86. Medicaid is a Government Health Insurance Program administered by the government of the United States and the various individual states and is funded by state and federal taxpayer revenue. The Medicaid Program is overseen by the HHS.

87. Medicaid was designed to assist participating states in providing medical services, durable medical equipment, and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the states obtaining the federal share of the payment from accounts which draw on the United States Treasury. *See* 42 C.F.R. §§ 430.0-430.30 (1994).

88. The Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396 *et seq.*, enacted the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8 (the "Act" or "Program" or "MDRP"). Under this Act, a drug is not eligible for Medicaid reimbursement unless the drug's manufacturer complies with the requirements of the Program, as administered by the Department of Health and Human Services ("HHS") through its CMS. *See* 42 U.S.C. § 1396r-8; *see also id.* § 1396a-u. Drug manufacturers wishing to participate in Medicaid must enter into and have in effect a National Drug Rebate Agreement ("NDRA") with HHS. Absent an NDRA, states cannot receive federal funding for the subject drug dispensed to Medicaid patients. As part of this program, manufacturers agree to rebate to the states a certain statutorily prescribed portion of the price of the drugs purchased by each Medicaid program in each state. *See* 42 U.S.C. § 1396r-8(a)(1).

89. In order for the Rebate Program to function as intended, manufacturers must

report their Average Manufacturer Price ("AMP") and "Best Price" for each of their covered drugs each quarter to CMS, and CMS and the State Medicaid programs share data in order to calculate rebates due. *See* 42 U.S.C. § 1396r-8(a). Simply speaking, the difference between the AMP and the Best Price is the basis for the rebates which a manufacturer must pay, or 15.1% of the AMP, whichever is greater. When properly calculated, "rebates ensure that states get at least the best prevailing wholesale price – and possibly even a much better price-for drugs they purchase for Medicaid beneficiaries." *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 221 (D.C. Cir. 2009)

90. The term "Best Price" is defined in relevant part as follows in the Act:

> The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under . . . [21 U.S.C. § 335(c)], the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding [certain enumerated programs not relevant here].
>
> * * *
>
> (ii) Special rules
>
> The term "best price" –
>
> (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
>
> (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;
>
> (III) shall not take into account prices that are merely nominal in amount; and
>
> (IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under [21 U.S.C. § 355(c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or

> governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

42 U.S.C. § 1396r-8(c)(1)(C)(i)-(ii).

91. CMS has over the years provided supplemental guidance to manufacturers regarding their "Best Price" obligations through program releases and training guides. First, the Model Rebate Agreement published by CMS states that "best prices shall be inclusive of *cash discounts*, *free goods*, *volume discounts*, and *rebates* (other than rebates under Section 1927 of the Act). . . . The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates *or other arrangements subsequently adjust the prices actually realized.*" CMS, Sample Rebate Agreement at 2, *available at* https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf (emphases added).

92. Second, CMS has published a series of Medicaid drug rebate program releases. These program releases clarify program requirements and respond to questions raised by manufacturers or states. In these, CMS has repeatedly stated its position:

> Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data must be adjusted by the Manufacturer if . . . other arrangements subsequently adjust the prices actually realized. Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the rebate agreement, included in the calculation of AMP and best price.

Medicaid Drug Rebate Program Release No. 14.

93. In other words, *even arrangements not specifically listed in the statute,* which have the *retrospective* effect of changing the price realized by the manufacturer – regardless of when that occurs – affect the previously reported best price and require a new amended report. In CMS's view, the only exclusions to best price are those specifically listed in the statute.

94. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. *See* Dependents' Medical Care Act, 10 U.S.C. §§ 1071-1106. The program is administered by the Department of Defense and funded by the federal government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

95. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Health Resources and Services Administration Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

96. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described above, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

97. The most basic requirement for reimbursement eligibility under Medicare is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); Medicaid, 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 410.50. Medical providers

are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See* 42 U.S.C. § 1395y(a)(1)(A).

98. It is axiomatic that CMS will also not pay a claim relating to reimbursement for goods or services that were not actually provided or paid for by the provider. As CMS Proposed Regulation 1503-P explains, "[i]t has been longstanding Medicare policy that in order to meet the general requirements for coverage under the 'incident to' provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies. . . . In accordance with our policy, providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because the overfill does not represent a cost to the provider." Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 40,040, 40,155 (July 13, 2010). The Medicare Policy Manual (publication #100-02) similarly notes, "[t]o be covered [by Medicare] supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing fir[m] he services or supplies." Medicare Benefit Policy Manual, 60.1 Incident to Physician's Professional Services (Dec. 1, 2003), *available at* https://www.cms.gov/manuals/Downloads/bp102c15.pdf. Practitioners in the health care field know this. As an American Health Lawyers Association guide explains, with citation to the Medicare Benefit Policy Manual, in order to obtain Medicare reimbursement, "[t]he drug must represent a direct financial expense to the physician or billing entity," which "means that the physician (or practice) must be paying for the drug." Medicare Part B Coverage, Billing and Payment for Drugs and Biologics Furnished in an Outpatient Setting, AHLA-PAPERS P04250707 (San Francisco CA, Apr. 25, 2007).

99. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

100. In other words, if a provider tells CMS or its agent that it provided goods or services in violation of the Anti-Kickback Statute, that were performed solely for the profit of the provider, and/or that violated another relevant law, CMS will not pay the claim.

101. Physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application, Form CMS-855A (for institutional providers), *available at* http://www.cms.gov/cmsforms/downloads/cms855a.pdf; Form CMS-855I (for physicians and non-physician practitioners) (effective 2001) (incorporated herein by reference), *available at* http://www.cms.gov/cmsforms/downloads/cms855i.pdf.

102. The "Certification Statement" that the medical provider must sign also contains the following provisions and requirements *inter alia*, for "initial *and continuous* enrollment in the Medicare program," and instructs that by signing the Certification

Statement, the provider "agree[s] to adhere to all of the requirements listed therein." Form CMS-855I (emphasis added).

103. Further, it states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to *meeting and maintaining* the Medicare requirements stated below." Form CMS-855I (emphasis added).

104. By signing the "Certification Statement," the provider certifies, *inter alia*, to the following:

> 1. I have read the contents of this application, and the information contained herein is true, correct, and complete. *If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare [program] immediately.*
>
> * * *
>
> 3. I have read and understand the Penalties for Falsifying Information. . . . I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application *or contained in any communication supplying information to Medicare* . . . may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or imposition of fines, civil damages, and/or imprisonment.
>
> * * *
>
> 8. I *will not knowingly present or cause to be presented a* false or fraudulent claim for payment by Medicare, and *will not* submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Form CMS-855I (emphases added).

105. The certifications made by the medical provider in the Provider Agreement, which are mandatory for Medicare enrollment, expressly create a continuing duty to comply with the conditions of participation in and payment by the Medicare Program. In particular:

(a) Prior to signing the Agreement, the provider is advised of the criminal, civil, and administrative penalties "for deliberately furnishing false

information in this application *to gain or maintain enrollment* in the Medicare program." Form CMS-855I, § 14 (emphasis added); and

(b) Among those penalties are criminal sanctions for fraud, concealment and any trick, scheme or device or scheme to defraud, any false or fraudulent statement or representation or any false writing or document, violations of the FCA, civil penalties for billing for a medical or other item or services that the provider knows or should know was not provided as claimed. *See id.* "Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit." *Id.*

106. The Provider Enrollment Chain and Ownership System ("PECOS") is a mandatory national enrollment system administered by CMS. It allows physicians and practice groups to enroll in Medicare or to make a change to their Medicare enrollment information online. Enrollment in PECOS requires a medical provider to recertify compliance with the Anti-Kickback Statute at that time. Specifically, when enrolling in PECOS, a medical provider either must complete the paper Medicare enrollment application and certification by completing the appropriate Form CMS-855A or CMS-855I (including certification of compliance with federal law and the Anti-Kickback Statute), or must complete an online enrollment, followed by submission of a two-page hard copy certification statement that requires the same certification as Form CMS- 855A and CMS-855I.

107. CMS requires all medical providers that receive Medicare reimbursements, and who have not submitted a CMS-855 enrollment form since 2003, to enroll in PECOS through either of the processes described above, both of which require contemporaneous recertification by the medical provider of compliance with federal laws, including the Anti-Kickback Statute.

108. The PECOS registration requirement is mandatory and governing regulations provide that medical providers not enrolled in PECOS will not receive Medicare reimbursements. Although the deadline for the application of that sanction was extended to January 3, 2011, by October 1, 2006, most medical providers had enrolled in PECOS (and, in so doing, had re-certified their compliance with federal law, including the Anti-Kickback Statute, as a condition of receiving Medicare reimbursements).

109. Other common circumstances regularly require medical providers to submit Forms CMS-855A or CMS-855I, along with contemporaneous certification of compliance with federal law and the Anti-Kickback Statute. For example, CMS requires the submission of a new CMS-855A enrollment form in the event of an acquisition, merger, or consolidation of a medical practice enrolled in Medicare.

110. Further, in the event of a change of ownership of a practice enrolled in Medicare, the new owner can either submit a new enrollment form (with certification), or assume the obligations of the existing provider agreement through an assignment process. Where an agreement is assigned to the new owner, the new owner specifically assumes the agreement subject to "all applicable statutes and regulations and to the terms and conditions under which it was originally issued." 42 C.F.R. § 498.18(d).

111. Institutional medical providers must also complete the CMS-855A certification whenever they reactivate a Medicare enrollment, voluntarily terminate a Medicare enrollment, revalidate their Medicare enrollment, or change any of their Medicare information, including: identifying information, practice location information, payment address and medical record storage information, ownership interest and / or managing control information, chain home office

information, billing agency information, special requirements for home health agencies, authorized officials, delegated officials, or information about adverse legal actions / convictions.

112. Similarly, physicians and other practitioners must complete a version of Form CMS-855I, including the certification of compliance with federal law including the Anti-Kickback Statute, whenever they do any of the following: change any of their Medicare information, including identifying information, practice location information, payment address and medical record storage information, information about individuals having managing control, final adverse actions/convictions, and billing agency information. Recertification of compliance is also required when physicians and other practitioners enroll with another fee-for-service contractor, reactivate their Medicare enrollment, voluntarily terminate their Medicare enrollment, or revalidate their Medicare enrollment. Physicians or other practitioners are also required generally to notify the government if any of the certifications or statements on the Form change.

113. As of October 1, 2006, the majority – *i.e.*, on the order of 60% – of all Medicare-eligible medical providers (including physicians and medical practices) had re-enrolled in Medicare since 2003, including for the above reasons; and in so doing, had re-certified their compliance with federal law, including the AKS, as a condition of receiving Medicare reimbursements.

114. Similarly, in order to participate in a State Medicaid program, a healthcare provider first must sign an enrollment form. The terms of the enrollment forms vary by state. For example, in Plaintiff State New Mexico, a provider must sign one of two forms, depending on the type of provider applying to participate in the Medicaid program: either the Medical Assistance Division Provider Participation Agreement ("MAD-PPA") Form 312 or the MAD-PPA Form 335. Both the Form 312 and the Form 335 "specif[y] the terms and conditions for the

provision of medical services to Medicaid clients," and both forms contain the same list of "terms and conditions." Among other things, participation in Medicaid (and payment from it) is conditioned on the provider's compliance with the federal and state anti-kickback statutes. Specifically, both forms state that "[i]f the provider obtains an excess payment or benefit willfully, by means of false statement, representation, concealment of any material fact, or other fraudulent scheme or devise with intent to defraud, criminal sentences and fines and/or civil monetary penalties shall be imposed pursuant to, but not limited to, the Medicaid Fraud Act, NMSA 1978, § 30-44-1 *et seq.* [New Mexico's analogue to the federal AKS], 42 U.S.C. § 1320a-7b [the federal AKS], and 42 C.F.R. § 455.23 [providing for withholding of payments in cases of fraud]."

115. By way of further example, in order to enroll in Plaintiff Georgia's Medicaid program, healthcare providers must certify that they "shall comply with all of the Department's requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, Including Part I, Part II, and the applicable Part III manuals." GA Statement of Participation § 2(A). The Part I manual, in turn, includes an anti-kickback prohibition as one of the state's "general condition[s] of participation" in the Medicaid program. (Part I Manual § 106(E)) (prohibiting "[a]ny offer or payment of remuneration, whether direct, indirect, overt, covert, in cash or in kind, in return for the referral of a Medicaid or PeachCare for Kids member"), *with* 42 U.S.C. § 1320a-7b(b)(1)(A) (prohibiting "solicit[ation] or recei[pt] [of] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind [] in return for referring an individual to a person [to] . . . a Federal health care program"). Georgia further conditions Medicaid providers' participation on their agreement to "the following term[] and condition[]": "Provider agrees that evidence of credit to the proper account by Payee's bank

pursuant to an EFT is sufficient to show acceptance of medical assistance payments under the Medicaid program within the meaning of the Official Code of Georgia Annotated, § 49-4-146.1(b)(2) [Georgia's analogue to the federal AKS]. Provider certifies by such acceptance that Provider presented the claims for the services shown on the Remittance Advice issued by the Department, and that the services were rendered by or under the supervision of Provider. Provider understands that payment will be from federal and state funds and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws." EFT Agreement ¶ 4.

116. In addition to properly enrolling and re-enrolling in the applicable Government Health Care Program, individual physicians providing services in conjunction with government health care program services such as Medicare and Medicaid submit claims using a CMS Form 1500 or a similar form. The CMS 1500 form, incorporated herein by reference, contains the following representations and notices: that the services rendered were "medically indicated and necessary for the health of the patient"; that the information on the claims form was true, accurate and complete; and, that the provider "understand[s] that payment and satisfaction of the claim will be from Federal and State funds, and that any false claims, statements or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

117. The CMS 1500 form also contains the following notice: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." The form also refers the provider to "Separate Instructions Issued by Applicable Programs." Because the States' Medicaid programs are funded in part with federal money, Medicaid fraud harms federal taxpayers (in addition to those in the states). To protect

the federal treasury, the CMS has promulgated federal regulations that require all state Medicaid plans to include "fraud prevention" programs. *See* 42 C.F.R. §§ 455.12-.23. The CMS's Medicaid fraud regulations further require all states to include the following statements "imprinted in boldface type" on all claim forms that any healthcare provider submits for reimbursement: "'This is to certify that the foregoing information is true, accurate, and complete. [] I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.'" *Id.* § 455.18(a).

118. When a provider submits a claim for payment, he or she does so subject to and under the terms of all applicable federal and state laws and pursuant to its certification to the government that the services for which payment is sought were delivered in accordance with such laws, to include without limitation the AKS and the FDCA.

FACTS AND ALLEGATIONS

A. Relator's Responsibilities at Defendants ABC and ABSG

119. Relator Mr. Mullen is the former COO (and before that CFO) of Defendant ABSG, a subsidiary of Defendant ABC, a former member of the ABC Corporate Ethics Committee, and was scheduled to join the ABC Executive Management Committee ("EMC"). He is currently a resident of Texas.

120. Mr. Mullen was hired by ABSG as CFO in May 2003. As CFO, his responsibilities included all of the financial operations of the company as well as implementation of all requirements to comply with the Sarbanes-Oxley Act. Mr. Mullen was also responsible for corporate operations, procurement and strategic planning. Reporting to Mr. Mullen in his CFO

role were ABSG's Vice President ("VP") of Finance/Controller, and VPs of Procurement Operations, Strategic Planning, and Planning and Analysis.

121. In September 2008, Mr. Mullen was promoted to the position of President, Distribution Services, ABSG. In that role he was responsible for four of ABSG's business units: a) ASD Healthcare (a distributor and wholesaler of nephrology products, blood plasma products, and vaccines); b) Besse Medical (a distributor of rheumatology and all other non-cancer drugs); c) Integrated Commercialization Services (a third-party logistics and clinical call center provider); and d) US Bioservices (a specialty pharmacy). These business units collectively generated over $5 billion in annual revenue for ABSG. The presidents of each of these business units reported directly to Mr. Mullen. ASD Healthcare, Besse Medical, and Integrated Commercialization Services shared an approximately 400,000 square foot distribution center in Louisville, Kentucky which Mr. Mullen was also responsible for. That distribution center was CGMP and ISO-9000 compliant and the US Bioservices specialty pharmacy facility was JCAHO certified, unlike the facilities operated by OSC and MII, as Mr. Mullen later learned.

122. In addition, Relator was also appointed to the ABC Corporate Ethics Committee; other members of that Committee were Mr. Yost (ABC CEO), Mike DiCandilo (ABC CFO), June Barry (ABC SVP HR), John Chou (ABC SVP Legal), Debbie Swartz (ABC Chief Compliance Officer), Chris Zimmerman (ABC VP Corporate Security and Regulatory Affairs), and Mr. Collis (former President, ABSG, former President of ABC Drug Company, now President and COO of Defendant ABC)).

123. This Ethics Committee met quarterly. The last two meetings of the Committee that Relator attended while employed by ABC were on February 17, 2010 and November 9, 2009.

124. In September 2009, Mr. Mullen was promoted to COO of ABSG, replacing Mr. Collis. Mr. Collis' job title had been President of ABSG. Mr. Mullen assumed the same exact job responsibilities that Mr. Collis had held but assumed the title of COO instead of President. In his capacity as COO, Mr. Mullen was responsible for all of ABSG's eight business units, which collectively generated $16 billion in annual revenue. Mr. Mullen's direct reports included the presidents of each of these business units and other corporate staff, including the heads of the information technology, human resources, finance, operations, procurement, strategic planning, and business development departments. Mr. Mullen reported to Mr. Yost, the CEO and a board member of ABC.

125. As COO of ABSG, Mr. Mullen also assumed, for the first time, *direct* responsibility for the business operations of ABSG's Oncology Business Unit (also known as the Oncology Group), which consisted of Defendants ION (a purported GPO), OSC (a wholesaler and distributor of oncology products), and MII (an oncology pharmacy, and subsidiary of OSC). Notably, ABC is the only major wholesaler that owns an oncology distributor (OSC), an oncology GPO (ION), and a purported oncology pharmacy (MII).

126. Throughout Mr. Mullen's seven-year career at ABSG, his performance and contributions were recognized and rewarded in the form of promotions, increased responsibility, increased compensation, increased stock option and restricted stock grants, inclusion in board of directors meetings, and participation as a speaker at a December 2009 Wall Street investor day conference. Until April 8, 2010, Mr. Mullen consistently received positive feedback from his superiors, including CEO Yost telling him that "things are going great under your leadership", he was "the right guy for the job", and that he "was doing what needed to be done" as COO to make ABSG successful.

127. ABSG's performance under Mr. Mullen bore this out. In ABC's fiscal year 2010 (October 1, 2009-September 30, 2010), ABSG delivered record performance that was ahead of the prior year's performance and 26% ahead of budgeted performance. ABSG thus finished the fiscal year ahead of budget and with record earnings.

B. As COO of ABSG, Relator Undertakes a "Strategic Review" of the Oncology Group

128. When Relator became COO of ABSG in September 2009, it signaled a major transition in the company. He was taking over from Mr. Collis (Relator's predecessor, and former boss at ABSG) who is now President of ABC. Mr. Collis had "founded" ABSG approximately 15 years before and put together the portfolio of companies and connected the business processes that, today, are ABSG. The oncology business group at issue in this First Amended Complaint (which included Defendants OSC, ION, and MII) were all acquired during Mr. Collis' tenure and, Relator believes, between 1994 and 2001.

129. In addition, Defendant ION was under relatively new leadership: Mike Martin, the President of ION from about 2005-2008, had been succeeded by Mark Santos in late 2008 or early 2009.

130. At the end of 2009 and the beginning of 2010, and in connection with his new responsibilities as COO of ABSG, Mr. Mullen conducted a comprehensive review of ABSG's businesses. As part of this review, Mr. Mullen interviewed senior managers, analyzed data, and took other steps to review the business organization, personnel, and practices, similar to the steps that are often taken during major organizational transitions. He also spoke with Mr. Collis, his predecessor, and former boss at ABSG, and frequently with Mr. Santos, who had recently been named as the new President of ION.

131. By January 2010, Mr. Mullen was prepared to implement a series of six strategic initiatives for ABSG. Mr. Mullen discussed these initiatives with ABC's CEO Mr. Yost and with Mr. Collis. He provided Mr. Collis with a PowerPoint presentation (and he may have done the same with Yost) summarizing these initiatives. He then presented these initiatives at a two-day Senior Management Retreat held in January 2010 in Cabo San Lucas. This retreat was attended by Mr. Mullen's senior staff, including: Gina Clark, ABSG SVP Marketing, Business Development; Robert Glasgow, ABSG SVP Procurement; Matt Johnson, ABSG SVP Strategic Planning and Acquisitions; Mitch McClain, ABSG SVP Finance; Rob Stone, ABSG Counsel; Dale Danilewitz, ABSG CIO; Meryl Harari, ABSG VP, Human Resources; Neil Herson, President, ASD Healthcare; Mick Beese, President, Besse Medical; David Cheetham, President, ICS; Mark Santos, President, ION; Dave Leverette, President, Oncology Supply; Mark Johnson, President, US Bioservices; Peyton Howell, President Consulting Services; Bob Mauch, President, Xcenda; Tracy Foster, President, Lash Group.

132. One of Mr. Mullen's six initiatives was a project to change the ION business model due to concerns that Mr. Mullen had about business and regulatory issues. It was Mr. Mullen's understanding that a GPO should act as a neutral contracting entity not aligned with any specific manufacturer and that GPOs should strike a neutral balance between the objectives of the manufacturers and the physician members of the GPO. Mr. Mullen further understood that it was not appropriate for a GPO to attempt to drive market share for, or to favor, one product or one manufacturer over another. Finally, Mr. Mullen understood that it was not proper, either operationally or from a compliance standpoint, that a GPO provide "free" services to its members or get deeply involved in their operations.

133. Mr. Mullen became concerned that ION was too close with its member providers, and was providing these members with free services that could be considered kickbacks. For example, ION would provide members free practice assessments and computer software and IT services, including many tools designed to help the doctors with the economics of their practices.

134. Mr. Mullen was also concerned that ION was too close with drug manufacturers, was allowing these manufacturers to use ION to drive market share for these manufacturers' drugs, and was improperly passing on price concessions to ION customers through ION and OSC. Especially concerning to Mr. Mullen were ION's public statements that one of its key deliverables was driving market share for drug manufacturers, such as a published statement by Jim Smith, who was VP of Sales for ION, that "[t]he bottom line is that ION can deliver on the two things that manufacturers want, which is market share and product promotion."

135. Following the Senior Management Retreat, Mr. Mullen again expressed his concerns about ABSG's oncology business model and regulatory issues to Mr. Collis. In addition, as discussed *infra*, he had further conversations with ABC CEO Yost. In at least one of those discussions, Yost noted there were aspects of the Oncology Group's business that he "would not want to see on the front page of the Wall Street Journal."

C. Relator Learns of the *United States ex rel. Westmoreland v. Amgen, Inc. and AmerisourceBergen Corporation* Lawsuit

136. In or around January 2010, as the books were being closed on ABSG's first quarter ending December 2009, Mr. Mullen saw on ABSG's books an allocation for approximately $3.5 million in legal expenses with which he was not familiar. When he inquired about these expenses, he was made aware, by the ABSG Senior VP Finance, that they related to an FCA lawsuit, *United States ex rel. Westmoreland v. Amgen, Inc. and AmerisourceBergen Corp.*, No. 06-10972-WGY (D. Mass.) ("Westmoreland Case"), in which the Relator alleged,

inter alia, that the administrative fees that Amgen had paid to ABC's nephrology GPO INN: a) were not "bona fide" service fees, and therefore did not fall within the AKS safe harbor for GPOs; and b) were, at least in part, "price concessions" that should have been, but were not calculated into the ASP of Aranesp (the Amgen drug at issue in the Westmoreland Case).

137. On more than one occasion in the winter to spring of 2010, Mr. Mullen reviewed at a cursory level, various materials (articles and the complaint itself) available online relative to the Westmoreland Case, and learned that the case involved Amgen, ABSG, ASD, and INN. At first, he was confident that if the Westmoreland Case presented any legitimate issue, ABC Legal, as well as Corporate Compliance and Regulatory Affairs, would be handling it appropriately. He was also confident that any serious concern raised by the Westmoreland Case would have been brought to and addressed appropriately by the ABC Corporate Ethics Committee, of which he was a member.

138. However, as discussed below, over time, Mr. Mullen ultimately became concerned that the Westmoreland Case had merit with respect to allegations that the administrative fees paid by Amgen to ABC's nephrology GPO INN: (1) were not "bona fide" and thus did not fall within the AKS safe harbor for GPOs (and so were kickbacks); and (2) could constitute a "price concession" that would affect the ASP of Aranesp (the Amgen drug at issue in the Westmoreland Case).

139. Moreover, Mr. Mullen recognized that the allegations made in the Westmoreland Case with respect to ABC's *nephrology* GPO and wholesale practice (INN and ASD Healthcare), were also applicable to ABC's *oncology* GPO and wholesale practice (ION and OSC). Notably, Aranesp is a drug that is used in both nephrology and oncology settings. Mr. Mullen further realized that the nature of the wrongdoing alleged in the Westmoreland Case was not confined to

Aranesp, but also applied to a number of different oncology drugs. In short, these practices were every day, standard operating procedure in ABSG's oncology business units (which included Defendants ION and OSC).

140. In March 2010, Mr. Mullen became aware of a deposition notice that had been issued to ABSG in the Westmoreland Case, regarding various aspects of ABSG's operations. The question of who should be the designated deponent(s) was under consideration, and Mr. Mullen appeared to be a logical choice given his position and history with ABSG.

D. Relator Presses Ahead With His Plans for the Oncology Business Group

141. On March 23, 2010, Mr. Mullen had a face-to face meeting with CEO Yost, during which Mr. Mullen provided an extensive "download" on the oncology business group and the status of ION. During that meeting, Mr. Mullen was very direct and adamant with Mr. Yost as to the serious issues that needed to be addressed and the changes that needed to be made; he expressed grave concerns in a number of areas including business, competitiveness, and regulatory exposure, and told Mr. Yost words to the effect that the situation was "worse" than Mr. Mullen had "thought." Among the many changes that Mr. Mullen discussed with and recommended to Mr. Yost were an overhaul of how the ION GPO operated and key changes in ION's personnel and organization. At the meeting, Mr. Mullen provided Mr. Yost with a PowerPoint presentation detailing his concerns and the solutions in progress.

142. At that same March 23, 2010 meeting, Mr. Yost expressed his confidence in Mr. Mullen, and informed Mr. Mullen that he would be joining Mr. Yost on the ABC EMC which consists of the top five executives in ABC.

143. As he had several times in the past couple months, Yost also wanted to make sure Mr. Mullen understood that the legal expenses for the Westmoreland Case were on ABSG's

books (which they were). Mr. Mullen was aware of the issue, and could not understand why Yost kept revisiting that point. They discussed the accrual of approximately $3.5 million in ABSG to cover anticipated legal expenses related to discovery in the case.

144. On March 26, 2010, Mr. Mullen received the largest grant of restricted stock and stock options since he joined ABSG in 2003. This grant of options was recommended by Mr. Yost and approved by the ABC Board of Directors.

145. On or about April 6, 2010, Mr. Yost and Mr. Mullen had a phone conversation regarding Mr. Mullen's view of ABSG's business and organizational risk. They discussed possibly peeling off two businesses under Mr. Mullen (Lash Group and Xcenda), which contributed less than 10% of ABSG's revenue and profit. Mr. Yost again inquired about *Qui Tam* Action legal expenses for the Westmoreland Case.

146. During February and March 2010, Relator also had several discussions with his predecessor Mr. Collis about ABSG's oncology business, Relator's concerns, and proposed solutions.

E. Relator's Stellar Career at ABSG Comes to a Sudden and Unexpected End

147. Mr. Mullen's career at ABC came to an abrupt end on April 8, 2010 during a scheduled meeting with Mr. Yost at ABSG headquarters in Dallas, Texas. Mr. Yost arrived at the meeting around 10:00 A.M. with John G. Chou, ABC's Senior VP, Secretary, and General Counsel (as well as a member of the ABC Corporate Ethics Committee), and June Berry, ABC Senior VP for Human Resources. During that meeting, which was held in the executive conference room, Mr. Yost informed Mr. Mullen that he was terminated. Mr. Yost provided no substantive explanation for Mr. Mullen's termination, saying only words very much along the

lines of "[w]e have a vision for this company and you're not part of it." Mr. Yost left the room after making that announcement.

148. Mr. Chou then provided Mr. Mullen with copies of an "enhanced" separation agreement that had already been executed on behalf of ABSG and described the provisions at a high level. That separation agreement failed to contain standard indemnity language protecting Mr. Mullen from liability in connection with his work at ABSG and also included a provision stating that Mr. Mullen had no knowledge of, nor had reported, conduct that was improper or inappropriate as of his termination date.

149. After Mr. Chou presented the proposed separation agreement to Relator, Mr. Mullen asked that Mr. Yost return to the executive conference room so that Mr. Mullen could wish him well. When he returned Mr. Yost again provided no explanation for Mr. Mullen's termination. Mr. Mullen was then allowed to return to his office to pick up a few personal items and then was immediately escorted from the building by two attorneys, Mr. Chou and Rob Stone (in-house counsel for ABSG); they told him that arrangements would be made for him to pick up his personal property at a later time.

150. Mr. Mullen was stunned and confused by his abrupt termination. After the April 8, 2010 meeting, Mr. Mullen downloaded the complaint in the Westmoreland Case and studied it in great detail. In doing so, Mr. Mullen became concerned that there was merit to another core allegation in the Westmoreland Case, namely that "overfill" contained in vials of Aranesp as manufactured by Amgen constituted a form of kickback and an unreported price concession that should have been, but was not, included in calculating the ASP of Aranesp. Mr. Mullen realized that such allegations were not only true in the context presented in the Westmoreland Complaint (specifically regarding the Aranesp in the nephrology setting), but had implications beyond the

nephrology business group. From his work at ABSG, and particularly the operational information he became familiar with as COO, Mr. Mullen realized that the same concerns were presented in how ION and OSC were selling and distributing injectable medications, including Aranesp, in the oncology setting. In addition, and perhaps most importantly, Mr. Mullen realized that there was a different, long-standing, and very profitable ABSG oncology business group practice involving overfill and numerous oncology drugs that created kickbacks, disguised discounts, and facilitated the billing of Medicare and Medicaid for free product.

151. On or about April 12, 2010, Mr. Mullen contacted Mr. Chou (as noted above, ABC's Senior VP, Secretary, and General Counsel, as well as a member of the ABC Corporate Ethics Committee). Relator explained that, despite the treatment he had been accorded, he wanted to convey some concerns regarding the allegations made in the Westmoreland Case and other business practices in the Oncology Group at ABSG, but he did not know how to have that conversation since he was no longer an employee. ABC through Mr. Chou agreed to extend Mr. Mullen's termination date until May 7, 2010, purportedly to facilitate the transfer of information from Mr. Mullen to ABSG. Mr. Mullen thereafter met with ABSG in-house counsel Rob Stone and provided him with extremely detailed written documentation of Relator's concerns on May 5, 2010. Concurrently, Mr. Mullen, through an employment lawyer he hired, negotiated certain changes to his separation agreement, including the important addition of an indemnity provision.

152. After Mr. Mullen's departure, ABSG replaced Mr. Mullen with James Frary. Prior to being appointed COO of ABSG, Mr. Frary was one of four general managers of an operating region within ABC – a position well below the seniority, scale, compensation level and complexity of ABSG COO. Mr. Frary had no experience at ABC in the specialty pharmaceutical

space and no general management experience over a large autonomous subsidiary, such as ABSG. Mr. Frary is also younger and less experienced than every one of his ABSG direct reports. Upon information and belief, ABSG selected Mr. Frary as Mr. Mullen's successor because it would be very difficult for someone with Mr. Frary's limited experience to discover or piece together the improprieties that Mr. Mullen had documented and brought forward to ABSG's and ABC's management.

153. Mr. Mullen's separation agreement with the company, which was signed on May 10, 2010, was the result of a series of negotiations between Mr. Mullen and ABSG General Counsel John Chou. In the final agreement, ABSG agreed to provide Mr. Mullen severance compensation, which was comprised of the following components: a) two years of his base salary (¶ 6(b)); b) a pro-rated performance bonus under the company's Annual Incentive Plan (¶ 6(c)); c) additional lump sums in cash (¶ 6(d)); and d) the cash value of certain restricted shares of company stock (¶ 6(f)).

154. Significantly, the negotiated agreement had a specific "carve-out," contemplating the possibility that Mr. Mullen might assist law enforcement and/or file a *Qui Tam* Action on his own behalf as well as that of the state and federal governments. While the first substantive paragraph of the agreement contains general release language, paragraph 13 explicitly states that:

> Nothing in this Agreement shall prohibit or restrict Employee from: (i) making any disclosure of information required by law; (ii) providing information to, or testifying or otherwise assisting in any investigation or proceeding brought by, any federal regulatory or law enforcement agency or legislative body, any self-regulatory organization, or the Company's General Counsel; or (iii) filing, testifying, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization.

155. As paragraph 13 makes clear, it was understood by ABSG that Mr. Mullen had serious concerns about the company's compliance, and that he had the right to disclose that

information to law enforcement, to assist in any investigation of alleged violations of law, testify about such matters, or file his own claims to "assist [] in a proceeding relating to an alleged violation of [law]."

156. On or about July 21, 2010, Mr. Mullen met with some of the undersigned counsel (who were, with the exception of local counsel, attorneys for Ms. Westmoreland) about the possibility of his filing a *Qui Tam* Action lawsuit. He subsequently retained such counsel. On or about October 14, 2010, Mr. Mullen met with two federal prosecutors and a federal investigator who asked to interview him in connection with the Westmoreland claims as well as other matters under investigation, and issued a subpoena for his attendance. On October 19, 2010, Mr. Mullen testified in a sworn deposition in the Westmoreland matter, pursuant to a subpoena issued by Relator's counsel. During the course of that deposition, Mr. Mullen truthfully testified that a) he had met with Ms. Westmoreland's attorneys, and b) that he had been interviewed by the government in connection with the Westmoreland claims and other matters. Both of these activities were protected activities within the meaning of the applicable federal and state anti-retaliation laws and expressly allowed by paragraph 13 of Mr. Mullen's severance agreement.

157. On October 21, 2010, Mr. Mullen through counsel filed his initial complaint in this case, in the United States District Court for the Eastern District of New York. This, too, was a protected activity under the anti-retaliation laws and expressly contemplated by paragraph 13 of his separation agreement.

158. Through clerical error in the District Court's Clerk's Office, Mr. Mullen's initial complaint was improperly placed on PACER rather than fully under seal, as it had originally been filed. As a result, counsel for ABSG learned of the complaint's existence, downloaded it from PACER, read it, held on to it for eight days without notifying the Court or the Clerk's

Office, then moved to dismiss the case for an alleged failure to file under seal. The Court denied Defendants' motion and, in the meantime, the case was removed from PACER and placed back under seal. ABSG has to this day failed to disclose what actions it has taken to avoid the document being disseminated or to destroy copies of the document which are no longer properly within its possession.

159. After learning of Mr. Mullen's protected activities (meeting with the Westmoreland lawyers and retaining them as his own counsel for his own action, debriefing the government, and filing his own *Qui Tam* Action complaint), ABSG retaliated against Mr. Mullen in December 2010 by withholding from him over $44,000 in bonus payments he was due under the terms of the severance agreement. When questioned about the reasons for withholding the bonus (which all ABSG bonus plan participants routinely were given), the General Counsel of the company, falsely and pretextually claimed that Mr. Mullen had not met the performance criteria to earn the bonus.

160. This statement was false in at least two respects. First, as the former CFO of ABSG, Mr. Mullen reviewed and approved the hundreds of performance bonuses awarded each year (most routinely), and is familiar with the performance criteria. There had never been any suggestion by anyone at the company, prior to its learning of his protected activities, that he had any performance issues whatsoever. Second, the record of Mr. Mullen's employment at all times prior to his termination was one of remarkable success, praise, and commendations, as reflected in contemporaneous emails and statements from the CEO and other sources. The claim that Mr. Mullen had "failed to perform" sufficiently well to earn his performance bonus was and is a pretext for the company's retaliation against his having engaged in protected activity under state and federal anti-retaliation laws, and activity expressly allowed by his severance agreement.

F. Defendants' Fraudulent Schemes

1. Overview

161. Mr. Mullen has first-hand knowledge of at least three separate fraudulent schemes that resulted in the filing of millions of false claims to government health insurance providers resulting in the overpayment of billions of dollars from the federal and state fiscs for oncology drugs.

162. First, Mr. Mullen has first-hand knowledge that since at least 2003 the ION GPO has not acted as a true GPO, was not entitled to the AKS safe-harbor protections for GPOs in any respect (including as to administrative fees and discounts), was collecting what were purported to be administrative fees that were, in fact, not for *bona fide* services and which were far in excess of fair market value, was sharing these excessive administrative fees with Defendant OSC so it could pass further discounts to customers, drive market share to certain drugs/manufacturers and thus earn even greater administrative fees for ION and the oncology business group, and was providing free services to physician members as a further inducement. These actions constituted illegal kickbacks and had the effect of illegally causing drug manufacturers to report an artificially high ASP (or other price such as AWP, AMP, WAC, and/or BP) to Government Health Care Programs.

163. Second, Relator has first-hand knowledge that ION, OSC, and MII engaged in an illegal overfill laundering scheme that was designed to, and did, monetize the free overfill and in the process pass illegal kickbacks, discounts, and price concessions to medical providers. The so-called MII "pharmacy" is a pharmacy in name only. In actuality, MII is a drug repackager and manufacturer that is not registered with the FDA. MII, in connection with ION and OSC, engaged in an illegal overfill laundering scheme designed to pass illegal kickbacks to medical providers and which also had the effect of over-reporting the ASP (and other prices) of the drug.

MII used sophisticated centrifuge and other equipment to extract all of the overfill from vials of drugs and filled syringes with this free product. The resulting pre-filled syringes were then sold to medical providers through OSC at a discount because, for example, for every 4 vials of drug, MII was able to make 5 pre-filled syringes. Not only do these actions constitute illegal kickbacks, but they had the effect of illegally causing drug manufacturers to report an artificially high ASP (or other price such as AWP, AMP, WAC, and/or BP) to Government Health Care Programs. Furthermore Defendants themselves failed to report ASP on these drugs as required by law.

164. Third, because MII is an unlicensed manufacturer and repackager, it, and its corporate parent (who is fully aware of this activity) are in violation of a host of state and federal laws, including Alabama's laws governing the operating authority of local pharmacies, and at least equally significant, the federal FDCA, 21 U.S.C. § 301 *et seq.* The FDA's regulation over drug manufacturers and repackagers pursuant to the FDCA is plenary. As set forth more fully below, MII has not only been operating intentionally below the FDA's radar screen, but it has violated any number of FDA mandated protocols designed to protect against contamination, product mix-ups, mis-identification, mis-labeling, deficient inventory control, and deficient lot number identification. The manipulation of sterile drug products – as they are removed from sterile vials and placed in pre-filled syringes (as in MII's operation), is an area of particular concern to the FDA. MII and its corporate parent have endangered public health through this unlicensed, unregulated repackaging operation, by reintroducing into commerce misbranded and adulterated drug products repackaged by MII's facility in Alabama. These drugs consist of very sensitive and potentially dangerous biologic drugs used to treat cancer patients.

165. These schemes involved several injectable biologic drugs manufactured by several different companies. The drugs at issue are all drugs used in one way or another to treat cancer or the side effects of chemotherapy and radiation or other cancer treatments.

166. ABC is the only major wholesaler who owns an oncology distributor (OSC), an oncology GPO (ION), and a purported oncology "pharmacy" (MII). ION and OSC, and MII were, in practice, operated by ABSG/ABC as a single business unit known as the "Oncology Group." While each company had its own financial statement (P&L) for purposes of accounting, internal financial statements reported the results of the Oncology Group; incentive compensation plans were based upon the results of the Oncology Group; and ABC regularly referred to the "Oncology Group" in public presentations and investor webcasts.

167. ABC was also the first wholesaler to jointly own an oncology GPO and a distributor.[2] OSC is the largest distributor to community oncologists in the country. ION is the largest oncology GPO in the U.S. Oncology Group revenue is approximately $8 billion per year, and operating income is approximately $190 million per year or approximately 11% of ABC's total revenue and 21% of ABC's operating income. Most importantly, in some years the Oncology Group accounted for virtually all of ABC's Operating Income growth. Further, the ION GPO alone accounts for approximately 10% of ABC's operating income, but less than two tenths of one percent of its revenue.

168. The community-oncology channel is large, growing, and accounts for a material amount of Medicare Part B drug expenditures. The community oncology channel, in total, is approximately $14-18 billion annually of which ABC owns about 45%-55% market share. Of

[2] Even now, McKesson is the only wholesaler besides ABC who jointly owns a GPO (National Oncology Alliance) and a distributor (OTN).

this total, Relator estimates that at least fifty percent is reimbursements from Government Health Care Programs such as Medicare and Medicaid.

2. **ION Is Not a True, Legitimate GPO: Illegal Remuneration Paid to ION and Kickbacks and Price Concessions Provided to Physician Customers by ABC Defendants Constitute Kickbacks and Undermine the Reporting of Accurate Pricing Used by Government Health Care Programs**

169. As set forth above, in theory, the purpose of ION, like other GPOs, is to permit physician customers to join together and aggregate their purchasing power and thereby receive favorable pricing. ION contracted with numerous pharmaceutical manufacturers to obtain favorable pricing to its GPO members. These pharmaceutical manufacturers and the drugs that they sold through ION include:

- Abraxis - Abraxane
- Amag - Feraheme (since this drug has no approved indication for oncology, market share-driven agreement between Amag and ION is presumably for an off-label use)
- Amgen - Aranesp, Neulasta, Neupogen
- APP - Granisetron (generic Kytril)
- Astra Zeneca - Arimidex, Faslodex, Zoladex
- Bristol - Erbitux
- Eisai - Aloxi
- Genentech - Avastin, Herceptin, Rituxan
- GlaxoSmithKline - Hycamptin, Zofran
- Hospira – Granisetron (generic Kytril)
- Lilly - Alimta, Gemzar
- Novartis – Zometa, Sandostatin
- Ortho Bio - Doxil, Procrit
- Pfizer - Camptosar, Ellence
- Pierre Fabre – Navelbine
- Roche /Genentech - Kytril
- Sanofi - Anzemet, Eligard, Eloxatin, Taxotere

170. Medical providers who were members of ION could purchase the above drugs (and others) from OSC utilizing their ION membership to access favorable GPO pricing.

171. Each of the manufacturers listed above, and others, paid "administrative fees" to ION ostensibly in return for administering their GPO contracts. Although there are some exceptions, the administrative fee paid to ION by the drug manufacturers was typically set at 3% of sales of the drug sold through ION and OSC.

172. Notably, however, there is virtually no cost associated with running the legitimate functions of the ION GPO. The true allowed costs for a GPO are those of administering contracts; this function is highly automated and not complicated or expensive. For the past seven years, ION had expenses of around $10 million annually, with a large percentage of these expenses not related to true contract administration. Indeed, even if the entire $10 million in expenses were valid (*i.e.*, related to contract administration), and one assumed a healthy, fair market profit of 25%, ION would have earned revenues of $12.5 million. Instead, ION had approximately $100 million of annual revenues, resulting in a profit margin of about $90 million or, cost plus 900%.

173. Where ION and the drug manufacturers set the administrative fee at 3% (or less) of sales, the administrative fee was presumptively exempt from AKS concerns (provided that all other conditions are met) under the HHS OIG AKS "safe harbor." However, most of the administrative fees paid to ION did not meet these conditions. Relator estimates that the true fair market value of the administrative fees would be around $300,000 to $700,000 per year per manufacturer and well below 1% of sales. Indeed, one manufacturer who refused to pay 3% and negotiated ended up paying ION an administrative fee of approximately $700,000 per year on approximately $2 billion of drug sales while other manufacturers were each paying far more than

$10 million (and as much as $40 million or more) in administrative fees annually. The difference was not in the time or expense required to fulfill the contract administration function; rather, it was whether the manufacturer's drugs faced competition and thus were "price sensitive." In other words, the manufacturer who negotiated the lower fee manufactured drugs that were single source, first line therapies and had no competitors, while the manufacturers who paid the higher fees had drugs that faced competition. Where a drug had true competition, it was "easy" for ION to promote one drug over the other by offering discounts for the manufacturer who paid ION the higher administrative fee and thus offered ION the higher profit. The ION GPO was of no value to the former manufacturer other than to administer GPO contracts. Other manufacturers, however, highly valued the GPO (*i.e.*, they paid approximately $60 million per year in administrative fees) as a vehicle to directly influence physician purchases and convert or launder administrative fees paid to the ION GPO into discounts to physicians on purchases from OSC.

174. Because the results of ION, OSC, and MII were consolidated into a single financial statement, OSC could price its products extremely aggressively, at times below acquisition costs, and recover the loss on the product sale through the collection of the ION administration fee paid to ION by pharmaceutical companies. Thus, for instance, if OSC sold a drug at a 1% loss, and ION earned a 3% administrative fee through the sale of that same drug, the Oncology Group as a unit would still earn a 2% profit from the transaction as a whole. This arrangement allowed OSC to "fund" particularly high discounts to select customers. For instance, members of ION's "Large Practice Program" received the most favorable pricing from OSC. The much more pervasive practice was one of extreme discounting that could not be

economically sustained if the distributor OSC had to stand on its own P&L, instead of the Oncology Group reporting together, as discussed above.

175. Early in Mr. Mullen's tenure as CFO of ABSG, he learned that a portion of the manufacturer-paid GPO administration fees earned by ION were being transferred to, and reflected in, the financial statements of OSC. Mr. Mullen discontinued this practice in or around Fiscal Year 2005 or 2006 due to his uncertainty with regard to what regulatory compliance issues this practice could cause and concerns that this practice skewed the financial results of ION and OSC, particularly with respect to Sarbanes-Oxley reporting requirements. However, the administrative fee was still fungible as a practical matter within the Oncology Group and ION continued to "fund" the discounts given by OSC through its administrative fee. In other words, while the administrative fees may no longer have been explicitly passed from the ION P&L to the OSC P&L, everyone at OSC knew that bigger discounts on their side would ultimately be covered by ION administrative fees and "wash" in the grand scheme (*i.e.*, the Oncology Group P&L) and, importantly, for the purposes of calculating incentive compensation which could be up to 150% of base salary. Among other issues caused by this practice, the "sharing" of GPO administration fees with OSC put those fees "in play" in that they could "fund" distributor discounts to individual customers and/or groups of customers, as well as affect the distributor's overall pricing and discounting strategy.

176. The operations of ION and OSC helped give the *appearance* of ION meeting the safe harbor rules under the AKS. In fact, however, this was a sham structure as: (1) ION and OSC did not operate independently, but rather operated as one business unit; (2) ION was not incurring legitimate and *bona fide* GPO costs that equaled the administration fee that it was paid; (3) executives of ABC, ABSG, OSC, and ION met regularly and jointly with physician

customers and with drug company representatives; (4) OSC was passing administrative fees earned by the ION GPO through to customers, and (5) the administrative service fees earned by ION were not fair market value.

177. As a result, drug companies, acting through ABC, ABSG, ION, and OSC, were able to target accounts and provide disguised discounts to physicians who purchased the particular drug company's product. For example:

- Executives of ABC, ABSG, and OSC regularly attended ION meetings with physician customers and maintained open, periodic communications with those customers. There was no "firewalling" of relationships or discussions between physician customers and the ION GPO and the OSC distribution company.
- Executives of ABC, ABSG, OSC and ION met regularly and jointly with drug company representatives to discuss state of the business and go forward strategies. Again, there was no firewalling of meetings or discussions.
- Field sales representatives of ION and OSC regularly engaged in joint visits to physician customer offices. These visits were also regularly **coordinated** with drug company field sales representatives. The field sales representatives utilized a sophisticated customer relationship management system enabling both the ION and OSC representatives to track customer orders and share notes on discussions and strategies with respect to those customers.
- Some ION employees were located in the OSC headquarters in Dothan, Alabama, in order to facilitate the joint, day-to-day shared operations of OSC and ION.

178. In addition to passing discounts to physician customers through OSC, ION's GPO contracts with a number of manufacturers enabled physicians to earn rebates based upon certain performance criteria. Many of those criteria were based upon market share, share growth, or similar metrics that could be considered "switching arrangements" in conflict with safe harbor rules.

179. The conduct outlined above implicates the FCA in two ways. First, the ABC companies have violated the AKS by offering kickbacks to providers as well as by accepting kickbacks (*i.e.*, administration fees in excess of fair market value) from the drug manufacturers. As noted above, violations of the AKS give rise to violations of the FCA.

180. Second, the ABC companies have undermined the true ASP reported by drug manufacturers to Medicare (and other prices relative to other Government Health Care Programs) and increased the profit to medical providers. As set forth above, since July 1, 2005, Medicare reimbursement has been set based upon a manufacturer reported ASP, which is reported quarterly by the manufacturer to the CMS. Manufacturers are required to deduct *all* "price concessions" from the calculation of ASP. 42 C.F.R. § 414.804(a)(3). Failure to do so results in an inflated ASP and Medicare overpaying for the drug. Among other things, the term "price concession" *excludes* "bona fide service fees," such as administrative fees paid to GPOs, *provided* that the fees paid represent fair market value for a *bona fide*, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, *and* that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug. 42 C.F.R. § 414.802.

181. In this case, the administrative fee paid to ION fail on both counts. First, it does not constitute fair market value for a *bona fide* service. Second, the pass-through of ION administrative fees to physicians via OSC is a price concession that should have been reported in ASP. ABSG's ownership of both OSC and ION facilitated this disguised discount transaction as ordinarily there would be no direct financial relationship between a GPO and medical provider to facilitate payment of the kickback. Moreover, the ABC Defendants offer other price concessions to medical providers.

182. The value of the administrative fees kickback, and the impact on ASP, is demonstrated in the following example:

- The drug company manufacturer reports to CMS that it sold 10,000, 50mcg vials for $1,000,000. Therefore, the average cost per vial is $1,000 and the average reported

cost per mcg is $20.00 per mcg. CMS (the Medicare administrator) would then set the reimbursement for the drug at $20.00 plus a statutory 6% allowance for physician profit (known as "ASP+6"). The physician therefore receives a total reimbursement of $21.20 for every mcg administered to a patient.

- However, because OSC passes through, on average, an additional 2% discount to medical providers (that was originally paid to ION in the form of an administrative fee), the true average cost per mcg in each vial is only $19.60.
- Medicare will reimburse $21.20/mcg for product that costs on average $19.60/mcg or ASP+8.1633% – *rather than* what is mandated in the statute establishing the Medicare ASP+*6%* methodology.
- Because the statutory intent is that physicians would be allowed, on average, a 6% profit, this scheme results in an increase in physician profit coming out of the public fisc of 36% (*i.e.*, the difference between 8.1633% and 6%).

183. Although the above numbers do not appear to be that large at a unit of measure level (*i.e.*, 1 mcg), they are substantial when one considers: (1) the dosage being billed (*i.e.*, if a single syringe contains 100mcg of drug, leading to a discrepancy of $42.40 per single dose syringe); and (2) the volume of patients being treated (an oncology practice treats hundreds of patients per day – and Medicare reimburses billions of dollars per year – using these types of biologics).

3. The ABSG Oncology Group's Overfill Laundering Scheme Involves Illegal Kickbacks and "Price Concessions" That Undermines Accurate Pricing by Government Healthcare Programs

184. MII is a subsidiary of OSC and is located in the OSC distribution center in Dothan, Alabama. MII handled approximately $300 million to $500 million worth of drugs every year. MII, however, does not fill patient prescriptions, nor does it conduct any of the other normal and customary activities of a true pharmacy. Rather, the sole purpose of the MII is to create pre-filled syringes from vials of drug purchased by OSC directly from the manufacturer, which OSC sells to MII in order to manufacture the pre-filled syringes, which MII subsequently sells back to OSC. OSC then sells these pre-filled syringes to its physician customers. This pre-

filled syringe repackaging program dates back to at least 2003, and the pharmacy was significantly expanded around 2006 due to the growth, success, and profitability of its activities.

185. Relator has first-hand knowledge that MII created pre-filled syringes of the following drugs, which were manufactured by the following pharmaceutical companies:

- Eisai Co./Eisai Pharmaceuticals: Aloxi (plonosetron hydrochloride), indicated for patients who may develop chemotherapy-induced nausea and vomiting (CINV);
- Sanofi-Aventis: Anzemet (dolasetron mesylate), indicated for the treatment of nausea associated with cancer treatment);
- Roche Laboratories, Inc./Genentech, Inc.: Kytril (granisetron hydrochloride), indicated to treat nausea and vomiting caused by chemotherapy or radiation; and
- Centocor Ortho Biotech, Inc./Johnson & Johnson (Ortho Bio): Procrit (epoetin alfa) indicated to treat anemia caused by chemotherapy (also indicated to treat anemia in patients with chronic kidney failure).

186. Every vial of injectable drug contains some amount of drug in excess of the labeled fill volume. This excess amount, or "overfill," is typically included in vials because a certain amount of the drug is expected to stick (or be "held up") in the vial or syringe when a medical provider withdraws the contents of a vial into syringe and administers the drug to a patient. Including a slight amount of overfill allows the medical provider to withdraw and administer the full labeled fill volume. According to the United States Pharmacopeia ("USP"), injectable drug vials may include a "slight excess" beyond the label volume to account for this issue.

187. Overfill is considered free product because it is not included in the price of the vial. It is also not reimbursable by Medicare. As made clear in the Medicare Reimbursement Policy Manual, "the cost of the drug" for which reimbursement is sought "must represent an expense to the physician." CMS Manual System, Pub. No. 100-02, *Medicare Benefit Policy* 60.1(A) (CMS/HHS June 18, 2004), *available at* http://www.hcca-physician-conference.org/past/2004/302/CMS%20Manual%20System.pdf ("CMS Manual, Pub. No. 200-

02"). Thus, Medicare will only permit a claim for reimbursement up to the labeled amount on the vial, and will not reimburse a claim related to overfill. As CMS recently explained in its Final Rule, Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011:

> We maintain that services or supplies reimbursed by Medicare under the "incident-to" provision should represent an expense incurred by the physician or entity billing for the drugs, service or supplies. Our policy clarifies that we will not pay for intentional overfill.

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170, 73,469 (Nov. 29, 2010) (updating 42 C.F.R. § 414).

188. The CMS Manual similarly notes, "[t]o be covered [by Medicare] supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing fir[m] he services or supplies." CMS Manual, Pub. No. 200-02, 60.1(A). Practitioners in the health care field know this. As an American Health Lawyers Association guide explains, with citation to the Medicare Benefit Policy Manual, in order to obtain Medicare reimbursement, "[t]he drug must represent a direct financial expense to the physician or billing entity," which "means that the physician (or practice) must be paying for the drug." Medicare Part B Coverage, Billing and Payment for Drugs and Biologics Furnished in an Outpatient Setting, AHLA-PAPERS P04250707 (San Francisco CA, Apr. 25, 2007).

189. MII, however, used sophisticated centrifuge and vacuum equipment to draw all of the contents from vials of drugs, including all of the free overfill amounts, and used that content to fill syringes. Thus, if a vial of a drug labeled "100mcg" actually contains 111mcg (with 11% "overfill"), every 10 vials draws would yield a "free syringe" for MII. For a drug such as Procrit which has been publicly reported to have had as much as almost 17% overfill for a number of years, and a low of about 11% overfill for other years, it could take far fewer vials to yield a

"free syringe" for MII. With oncology drugs, one "free" dose can be worth anywhere from several hundred to several thousand dollars in reimbursement from a Government Health Care Program.

190. OSC would then sell these pre-filled syringes (including the syringes made from free product) to medical providers, who administered the free product to patients. Because MII's overfill laundering practice allowed it to create pre-filled syringes out of free product, OSC's profits were significantly and materially enhanced. OSC would pass a portion of this windfall overfill profit on to providers in the form of an additional discount or price concession. Thus for example, where MII was able to extract 11% overfill, OSC would derive a 11% price advantage by selling, to physicians, these pre-filled syringes instead of simply selling the vials it had purchased from the manufacturer. OSC would price the syringes to "split" the 11% overfill benefit with the physician, inducing him to buy the pre-filled syringes and enabling him to make a greater profit. ION could also earn a GPO administration fee for the product sold in the syringe, even though it was "free."

191. This practice is an inducement and kickback to physicians facilitated by the joint ownership of MII, ION, and OSC. MII effectively laundered and monetized the overfill in an attempt to "shield" the physician, the drug company, and ABSG from regulatory exposure. A physician receives a 100mcg-labeled pre-filled syringe containing a true 100mcg labeled dose of product which it then bills to the insurer, *e.g.*, Medicare. On its face, no "free" product *appears* to have been billed by the physician. *However*, the syringe was purchased, by the physician, at a price concession due to the overfill benefit derived by MII's laundering scheme. This price concession constitutes illegal remuneration in violation of the AKS and the FCA. The process described above results in Medicare and Medicaid being billed for and

reimbursing physicians for free product – exactly the practice condemned by CMS, as noted *supra*.

192. Moreover, this price concession undermines the ASP (or other pricing) calculation reported on a quarterly basis to CMS, leading to artificially inflated ASPs and other prices. The value of the kickback and the impact on ASP is demonstrated in the following example:

- A drug company manufacturer reports to CMS that it sold 10,000, 50mcg vials for $1,000,000. Therefore, average cost per vial was $1,000 and the average reported cost per mcg was $20.00 per mcg. CMS (the Medicare administrator) would then set the reimbursement for the drug at $20.00 plus a statutory 6% allowance for physician profit (known as "ASP+6"). The physician would receive a total reimbursement of $21.20 for every mcg administered to a patient.
- However, if those vials actually contain 55.5mcg (11% overfill), and the overfill is extracted and used through Defendants' overfill laundering scheme, the true cost per mcg in each vial is $18.02.
- As a result, Medicare reimburses $21.20 per mcg for product with an average sales price of $18.02 per mcg, or ASP+17.65% – which is almost triple the physician profit provided for under the mandated ASP+6% methodology.

193. As set forth above, because MII operated as a repackager and manufacturer, it was required to submit ASP information – including the ASP for each NDC of injectible drug it sold, and the units of each NDC sold – on a quarterly basis to the CMS. MII did not submit this information for any of the drugs that were part of its overfill laundering scheme – largely, because MII was operating as an unregistered and unlicensed repackager and manufacturer, and because the pre-filled syringes it produced were not assigned any NDC codes. Had MII submitted accurate ASP information, as it was (and is still) required to do, this would have reduced the reimbursement rate that Medicare paid out for these drugs from their artificially inflated rates. Moreover, because the pre-filled syringes manufactured by MII were never assigned a valid NDC, to the extent that any claim for reimbursement for these syringes filed

pursuant to a CMS 1500 claims form included an NDC code for the drug administered – that claim was materially false.

4. The MII "Pharmacy" Is in Fact an Unregistered, Unlicensed Drug Repackager and Manufacturer Whose Primary Function Is To Repackage Vials of Drugs (Including Single-Dose Vials Without Preservative) into Pre-Filled Syringes, Without Complying With the FDA's Requirements With Respect To Manufacturing and Safety Protocols, Thereby Endangering Public Health

194. In addition to the schemes described above, Defendant MII, with the full knowledge of its corporate parent ABSG, has engaged in, and continues to engage in, a massive deception of the FDA and fraud on the Government Health Insurance Programs. In sum, by holding out to the public and to regulators that MII is a "pharmacy," MII and ABSG have effectively avoided the FDA's oversight and jurisdiction over its repackaging operation of massive quantities of different drug products.

195. Hundreds of thousands of pre-filled syringes are shipped from MII every year, to wholesalers owned by ABC, for redistribution and resale. The volumes of drugs leaving the unregistered MII facility are staggering: Relator estimates based upon public information and data in his possession, for example, that between 20%-30% of *all Procrit and Aloxi* administered by community oncologists in the United States (*i.e.* Medicare Part B) came from the MII repackaging operation.

196. Not only is MII not registered with the FDA, but its pre-filled syringe products are not even listed on the FDA list of approved drugs. A comparison of two comparable products, Amgen's Aranesp pre-filled syringes and Ortho-Biotech's Procrit, are revealing. These are two drugs are substantially similar ESA drugs and competitors in the market place. Amgen's Aranesp vials and Aranesp pre-filled syringes *have separate NDC numbers*, as required by FDA law and regulation. A review of the FDA's listings for Procrit, however, shows that only Ortho-

Biotech's vials are listed with the FDA. In other words, the pre-filled syringes of Procrit manufactured by MII are not listed – at all – as approved drug products by the FDA.

197. Thus, the MII "pharmacy," which handles hundreds of thousands of dosages of dangerous biologic oncology drugs every year, operates free of the FDA's oversight, putting public safety at risk through the distribution of misbranded and adulterated drugs, rendering false and fraudulent all claims of reimbursement flowing from the sale of MII's pre-filled syringes.

198. MII fails to meet the definition of a traditional "pharmacy." MII does not receive or fill individual prescriptions for individual patients. MII does not dispense drugs to patients, nor does it bill insurance companies or patients for co-payments, as normal pharmacies do. Rather, MII sells pre-filled syringes, *in bulk*, to drug *wholesalers* such as its sister company OSC and Pharma-Buy (another ABC-owned entity), for ultimate resale to healthcare providers. The Alabama Practice of Pharmacy Act makes clear that MII is a manufacturer, not a pharmacy: "The distribution of inordinate amounts of compounded products without a prescriber / patient / pharmacist relationship is considered manufacturing." 205 § 34-23-150(5).

199. As set forth above, the FDA similarly has stated that some "establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the [FDCA]." FDA Compliance Policy Guides 460.200. "Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers." *Id.*

200. The FDA Guidelines further state:

> [W]hen the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining

whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.

* * *

6. Using commercial scale manufacturing or testing equipment for compounding drug products.

* * *

7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

FDA Compliance Policy Guides 460.200.

201. MII's activities meet all three of the above listed criteria for treatment as a drug repackager or manufacturer. First (item 1, above), MII is compounding, *i.e.*, repackaging, thousands of pre-filled syringes every day and, as discussed above, is not receiving valid prescriptions from physicians. Second (item 6, above), MII uses large-scale commercial vacuum and centrifuge equipment to extract drugs from manufacturers' vials in a facility designed and built solely for that purpose. Third (item 7, above), MII sells the pre-filled syringes it produces to OSC and PharmaBuy, not to individual patients. Indeed, *these ABC-owned wholesalers constitute 100% of MII's customers – it has no other customers at all, and does not engage in any retail business.*

202. Defendant ABSG is fully aware of the repackaging and manufacturing activities of MII, having approved, in 2007, the funding and construction of an entirely new production facility in Dothan, Alabama, where the pre-filled syringes are produced. Moreover, from a compliance and oversight perspective, ABC was already well familiar with the FDA's rules governing repackagers, by virtue of its owning and operating at least one repackaging subsidiary,

Anderson, and having at least two labeler codes assigned to ABC as part of NDCs for products ABC repackages.

203. By posing as a pharmacy, MII has intentionally avoided registration with the FDA for its actual business activities of repackaging drugs. There are multiple misbranding violations caused by this scheme, and serious risks of patient harm and adulteration of drug products through unregulated drug repackaging and distribution.

204. The drugs in pre-filled syringes leaving the MII facility are misbranded in at least the following ways:

- They are produced at an unregistered drug repackaging and manufacturing facility, in violation of the FDCA, specifically 21 U.S.C. § 360(b), which requires annual registration of all drug manufacturers. (The pharmacy exception to this requirement, set forth in 21 U.S.C. § 360(g)(1), does not apply, because MII is not a "retail" pharmacy as described in the statute.)

- They are unapproved "new" drug products for which no supplemental New Drug Application (sNDA) has been filed, in violation of Sections 505(a) and 301(d) of the Act [21 U.S.C. §§ 355(a), 331(d)]. *See, e.g.*, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075794.htm (FDA Warning Letter No. 2006-NOL-04 to Southern Meds Joint Venture, LLC: "Your firm's compounded products are unapproved new drugs, and their introduction or delivery for introduction into interstate commerce violates [the FDCA]"); *In re Establishment Inspection of Wedgewood Village Pharmacy, Inc.*, 270 F. Supp. 2d 525, 543-44 (D.N.J. 2003), *aff'd*, *Wedgewood Village Pharmacy v. United States*, 421 F.3d 263 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions for the new drug . . . provisions. Neither pharmacies nor compounded drugs are expressly exempted."). *See also* FDA Letter NWE-06-07W (compounded drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p), because they are not generally recognized, among experts . . . as safe and effective) (internal quotation marks omitted).

- They are drug products not separately listed on the required FDA listing of drugs, as required by the FDCA, specifically 21 U.S.C. § 360(j). A search of the NDC Directory shows that there are no NDCs for the pre-filled syringe presentation of Aloxi, Anzemet, Granisetron, or Procrit – the four drugs repackaged by MII. MII nonetheless sells hundreds of thousands of pre-filled syringes of each of these drugs every year.

- They are drug products for which the NDC numbering system fails to account for the repackaging process. Section 505(D) of the FDCA, codified at 21 U.S.C. § 355d, requires that drugs in interstate commerce have "standardized numerical identifiers" or SNIs. According to the FDA itself: "The SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) (as set forth in 21 CFR Part 207) that corresponds to the specific drug product (including the particular package configuration) combined with a unique serial number, generated by the manufacturer or repackager for each individual package." FDA, Guidance for Industry-Final, *Standards for Securing the Drug Supply Chain-Standardized Numerical Identification for Prescription Drug Packages* (Mar. 2010), *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm (footnote omitted). In language directly applicable to MII's operation, this guidance further states: "In the case of repackaged drugs, each package type should have an NDC that corresponds to the repacker or private label distributor for whom the drug is repacked and to the new package configuration." *Id.* at n.4. *MII's repackaged drugs contain no sNDCs that correspond to the repacker (MII), making it impossible for the FDA or the public to meaningfully authenticate, track, and trace any of the drugs repackaged by MII into pre-filled syringes, as required by law*. Moreover, as set forth above, because the pre-filled syringes manufactured by MII were never assigned a valid NDC, to the extent that any claim for reimbursement submitted on a CMS 1500 claim form contained NDC information, that claim was materially false.

- They are produced in a manner that makes it impossible to maintain appropriate labeling, lot number control, and drug pedigree. (By creating an extra dose of drug out of overfill in vials, inevitably drug product is blended with drug product from other vials, making tracking issues virtually impossible, not to mention the cross-contamination potential created by such pooling of product.[3])

205. Upon information and belief, the MII facility is also distributing adulterated drug products, not just misbranded products. The MII facility has never demonstrated – to anyone – compliance with CGMP because it has treated itself (and posed) as a traditional pharmacy not subject to FDA inspection. Mr. Mullen, who visited the MII site as COO of ABSG, believes that both in the past and at present, the MII facility would not pass a routine inspection under the CGMP standards of the FDA.

[3] It should also be noted that Procrit, one of the drugs repackaged by MII, is subject to an FDA black box warning and therefore it is critical that this warning be included with MII's pre-filled syringes.

206. The FDA's CGMP requirements are set forth in 21 C.F.R. §§ 210 and 211. These can fairly be summarized as a comprehensive list of manufacturing protocols designed to ensure product and patient safety. These protocols include such important items as the requirement of a quality control function with appropriately trained personnel (subpart B), the design, sanitation, and maintenance requirements for the building sites where the drugs are manufactured (subpart C), the design, construction, and maintenance of the equipment used to manufacture or repackage the drugs (subpart D), the testing and protocols governing drug containers (subpart E), production and process controls, including the requirements for proper testing, sampling, and control of microbiological contamination (subpart F), packaging and labeling control, including procedures to determine if the drugs' expiration dating system is reliable (subpart G), warehousing and distribution requirements (subpart H), laboratory controls, including "stability" testing to determine if the proper amount of active ingredient is contained in each unit of drug (subpart I), and record-keeping and reporting requirements, including the maintenance of production and batch control records and equipment cleaning logs (subpart J).

207. With respect to the manufacture of pre-filled syringes in particular, the FDA has issued the following guidance, among many other requirements:

i. Establishing an aseptic production environment including, but not limited to, effective disinfection of all surfaces in the production area. Air filtration must also be properly designed and effective. Periodic testing and monitoring of aseptic conditions is required.

ii. Establishing a quality control process to ensure quality of drug product containers, packing material, labeling, and drug product.

iii. Preparation of batch production and control records for each batch of drug product containing information including documentation of each significant step in the process and including lot codes for the drug product and syringes used and specimens of finished product labeling.

iv. Routinely calibrate equipment according to a written program as well as maintain written records of equipment cleaning, maintenance, and use.

v. Employees engage in the manufacturing, processing, packing, or holding of a drug product must have training in CGMP.

vi. Establish a written testing program to assess the stability of the injectable drug product in the pre-filled syringe.

vii. Assure all drug products meet applicable standards of identity, strength, quality, and purity at the time of use by establishing an expiration date determined by appropriate testing.

Compliance Policy Manual, Chapter 56.

208. The FDA has consistently taken the position that failure to conform to these practices renders the drug produced "adulterated" within the meaning of the FDCA. Mr. Mullen believes, based upon his own visual touring of the MII "pharmacy" facility – which prior to 2007 was slightly larger than a large closet – and his responsibility for another CGMP/ISO-900 facility, that the MII facility does not meet these CGMP standards. Moreover, the MII facility did not have standard operating procedures that were consistent with a manufacturer and repackager. As a result, upon information and belief, potentially all of the pre-filled syringes produced by MII may be adulterated.

209. The FDA has recently stated that it has a great "concern about the manipulation of approved sterile drug products, especially when the sterile container is opened or otherwise entered to conduct manipulations such as dissolving, diluting or aliquoting, *refilling*, resterilizing, or *repackaging in new containers.* The moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard(s) are compromised and no longer valid." FDA Compliance Policy Guide 446.100 (emphasis added), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074385

.htm. This is precisely the activity MII is engaged in, outside of the view of the FDA: the opening (every day) of thousands of vials of drugs from the manufacturer, in order to transfer the contents to pre-filled syringes, solely for the purpose of generating additional profit for MII and its parent corporation. In addition, Mr. Mullen believes that if inspected, the MII facility would be unable to establish compliance with the CGMP standards – precisely because it has been operating illegally and treating itself as immune from those standards ever since ABSG acquired the company and turned it into a repackaging operation.

210. One issue highlights the risk to public safety presented by this unregulated activity, concerning the drug Procrit. Procrit is a genetically engineered version of erythropoietin or EPO, a human protein that stimulates the production of oxygen-carrying red blood cells. Procrit is a member of a class of drugs referred to as ESAs, or erythropoietin stimulating agents, which includes Epogen and Aranesp (Amgen). (ESAs are subject to an FDA black box warning.) ESAs are used to treat anemia experienced by patients with chronic kidney disease (CKD) and cancer patients with chemotherapy-induced anemia, among other conditions.

211. Pure Red Cell Aplasia ("PRCA") is a rare, but serious (potentially fatal), side effect of EPO which results in severe anemia when the patient develops antibodies to EPO. There were a significant number of PRCA cases in patients receiving EPO identified by regulatory authorities, manufacturers, and academics between 1999 and 2004 in Australia, Canada, Europe, and Asia. Several studies were conducted to determine the cause of these EPO-associated PRCA cases. (The studies happened to focus on patients being treated for chronic kidney disease.)

212. Studies determined that there were a number of potential contributing factors to the incidence of PRCA, including: route of EPO administration, whether or not the EPO

contained Albumin or Polysorbate 80, and *whether or not the EPO was delivered in a pre-filled syringe.* With respect to the pre-filled syringes, the studies cited two concerns: 1) Rubber plungers of pre-filled syringes released leachates into the contents of the syringe causing an alteration of the EPO contained in the syringe (Ortho-Biotech switched to a Teflon-coated plunger to address this issue); and 2) silicone lubricant used in pre-filled syringes interacted with the EPO contained in the syringe.

213. Because the MII facility in unregulated and uninspected, neither the FDA nor the consuming public has any idea whether MII's pre-filled syringes of Procrit are using the types of plungers and lubricants that have been linked to PRCA and caused concern in the public health field – about this potentially fatal condition. MII produces hundreds of thousands of Procrit pre-filled syringes every year, and yet, as of today, the public has no idea whether those syringes are manufactured and handled in a way that is safe. This is only one of the risks presented by MII's clandestine operation. Relator believes, upon information and belief, that there are serious public health concerns raised by MII's operating an unregistered, unlicensed, uninspected drug repackaging operation, distributing "new" drugs that are neither listed nor approved by the FDA.

G. Claims Submitted and Damages Caused to Government Health Care Programs

214. Defendants' actions described above have caused the submission of false and fraudulent claims, and they have made and used, and/or caused to be made and used, false records and statements for the purpose of having false and fraudulent claims submitted to, paid and/or approved, by Government Health Care Programs including Medicare.

215. Among other things, claims filed with the Government Health Care Programs because of Defendants' actions have contained false and fraudulent statements and material omissions. Defendants knowingly caused medical providers to present for payment and approval false and/or fraudulent claims to officers of the United States and the state governments

including, without limitation, claims submitted to Medicare and/or Medicaid on CMS Form 1500 claim forms and other claims submitted for payment from government funds.

216. Defendants' actions have also caused medical providers who received price concessions as a kickback to violate the AKS, the conditions of their receipt of Medicare (and other Government Health Care Programs) reimbursements, including the AKS, and their certification that they would comply with the AKS as a condition for the receipt of government reimbursements.

217. Defendants' actions have also caused medical providers who received price concessions as a kickback to file false certifications with Government Health Care Programs, including pursuant to Form CMS-885 that they were in compliance and/or would comply with the Anti-Kickback Statute.

218. Furthermore, in order to receive reimbursement from certain Government Health Insurance Programs, doctors must include NDC information on the CMS Form 1500 claim forms submitted to Government Health Insurance Programs. Defendants' actions have caused medical providers to submit false claims on CMS Form 1500 claims forms because there was never any NDC assigned to the pre-filled syringes manufactured by MII and sold through OSC. Accordingly, any NDC information included on the CMS Form 1500 was materially false and inaccurate.

219. Government Health Insurance Programs have unwittingly paid for drug products that have been misbranded, adulterated, and placed in commerce without FDA approval, due to MII's repackaging operation in Dothan, Alabama.

220. There is evidence that Defendants have caused the majority of medical providers purchasing oncology drugs from OSC to provide false certifications on Forms CMS-855A and

CMS-855I during the time that medical providers purchased oncology drugs through OSC, and to submit false or fraudulent claims for reimbursement to Government Health Care Programs, including through CMS Form 1500.

221. Any medical provider who received kickbacks from Defendants prior to re-enrollment in Medicare was caused by Defendants to submit (and did in fact submit) a false certification of compliance with federal law, including the Anti-Kickback Statute, upon re-enrollment in Medicare. When the providers signed these re-enrollment forms, they knew that they would be accepting kickbacks from Defendants in violation of the AKS. Also, as a result of Defendants' conduct, all Medicare claims submitted by those medical providers after such false certification was executed constituted false or fraudulent claims that Medicare should not and would not have paid.

222. Defendants' conduct caused medical providers to submit false provider certifications that they were in compliance with the federal and state Anti-Kickback Statutes.

223. Compliance with the AKS is a condition to payment by the Medicare Program, and by other Government Health Care Programs. By virtue of Defendants' GPO and overfill laundering fraud, the Medicare Program and other Government Health Insurance Programs reasonably and foreseeably were billed for and paid medical providers for a higher reimbursement amount than they were entitled to.

224. By way of example, Relator offers the examples above of manufacturers, drugs, administrative fees, and free pre-filled syringes as representative of claims submitted and damages caused to the Medicare Program.

225. In addition, every claim submitted to a Government Health Care Program that contains an inflated ASP or other price is a false or fraudulent claim. Relator knows, or has a

good faith basis to believe, that manufacturers were not including administrative fees as a reduction in ASP. Relator knows of no instance that a manufacturer conducted a fair market value study, in conjunction with ION, to determine what portion of the administrative fee would not be considered to be for a *bona fide* service at fair market value and, therefore, should be deducted from ASP. The amounts paid, on their face, are not fair market value. Moreover, Defendants' overfill laundering scheme, and their failure to submit any ASP information to CMS on a quarterly basis, caused the ASPs for the drugs at issue to be artificially inflated.

226. The community oncology channel is large, growing, and accounts for a material amount of Medicare Part B drug expenditures. The community oncology channel, in total, is likely $14-18 billion *annually* of which Government Health Care Programs including Medicare account for at least 50% of the annual reimbursements. ABC owns about 45%-55% market share in community oncology.

227. ABSG sold billions of dollars of these drugs each year and hundreds of millions worth of these drugs moved through MII, the oncology pharmacy, in the form of hundreds of thousands of pre-filled syringes. The misconduct has been ongoing for years, involves billions of dollars in reimbursements, and millions of claims.

CLAIMS FOR RELIEF ON BEHALF OF THE PLAINTIFFS UNITED STATES OF AMERICA AND THE NAMED STATES

COUNT ONE
VIOLATIONS OF THE FEDERAL FCA
31 U.S.C. § 3729(a)(1)(A), (B), and (G)

228. Relator restates and realleges the allegations contained in paragraphs 1-227 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

229. Since at least 2003, Defendants ABC, ABSG, ION, OSC, and MII knowingly presented or caused to be presented false or fraudulent claims to Government Health Care Programs and knowingly made, used, or caused to be made or used, false statements to get said claims paid by Government Health Care Programs. As a result of these illegal schemes, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A)-(B).

230. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of 31 U.S.C. § 3729(a)(1)(A)-(B).

231. In particular, these claims were also false or fraudulent and statements and records were false because the cost of the drug was inflated due to Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product. In addition, such claims were false and/or fraudulent because the reimbursement rate at which CMS or the states paid such claims, *i.e.*, the ASP or the Average Manufacturer's Price for the drug, was inflated because manufacturers failed to include in the ASP calculation reported to CMS the price concessions that were passed through from the ABSG Oncology Group to medical providers through the administrative fee and overfill laundering fraudulent schemes, and Defendants failed to file or report any ASPs to CMS for the drugs being repackaged by MII.

232. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating 31 U.S.C. § 3729(a)(1)(A)-(B), Defendant's conduct violated 31 U.S.C. § 3729(a)(1)(G).

233. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims.

234. Defendants ABC, ABSG, ION, OSC, and MII caused such claims to be submitted for reimbursement when Defendants knew (within the meaning of the FCA) that because of their offering price concessions as a kickback such items or units were not eligible for reimbursement, in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

235. Providers submitted such claims as a natural and foreseeable result of the illegal activity of Defendants described in this First Amended Complaint.

236. Defendants knowingly caused to be presented false or fraudulent claims resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

237. Defendants knowingly caused to be presented false or fraudulent claims for drugs that were misbranded and adulterated under the FDCA.

238. Government Health Care Program officials, their contractors, carriers, intermediaries, and agents, paid and approved claims for payment that should not have been paid or approved.

239. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from

officials with Government Health Care Programs, and other government officials, their contractors, carriers, intermediaries, and agents, in order to induce payment of the false and fraudulent claims.

240. Government Health Care Program officials and their contractors, carriers, intermediaries, and agents, would not have paid the claims had they known the truth.

241. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT TWO

CONSPIRACY TO DEFRAUD
FEDERAL FCA, 31 U.S.C. § 3729(a)(1)(C)

242. Relator restates and realleges the allegations contained in paragraphs 1-241 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

243. Through the acts and omissions described in this First Amended Complaint, and from on or before at least 2003 to the present, Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal government by having false or fraudulent statements, records, certifications, and claims submitted to, paid and approved by Government Health Care Program officials, their contractors, carriers, intermediaries, and agents.

244. From on or before 2003 to present, Defendants ABC, ABSG, ION, OSC, MII, and non-parties known and unknown including pharmaceutical manufacturers, conspired to defraud the United States by knowingly offering kickbacks to medical providers including in the form of price concessions and by understating the true ASP of the drugs.

245. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to submit false certifications to Government Health Care Programs, including the Medicare and Medicaid Programs, that the provider was in compliance with state and federal laws, including the Anti-Kickback Statute and the FDCA.

246. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to present, make, and/or use claims, thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

247. By virtue of their conspiratorial agreement, Defendants caused to be presented, made, and/or used false or fraudulent claims, and/or false records or statements, including provider certifications, to Government Health Care Programs, including the Medicare and Medicaid Programs, causing the United States to suffer significant damages.

248. Defendants knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Government Health Care Programs. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of the drug to be made. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of Defendants. Said claims were improper and should not have been made because of Defendants' actions in placing in interstate commerce repackaged new drug products which were misbranded and adulterated under the FDCA. Said actions constitute violations of 31 U.S.C. § 3729(a)(1)(C).

249. Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of the drug. It is illegal to pass the

costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Government Health Care Program and it is also illegal to falsely report (or fail to report) the true cost of a drug. Said actions constitute violations of 31 U.S.C. § 3729(a)(1)(C).

250. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims.

251. Defendants caused such claims to be submitted for reimbursement when Defendants knew (within the meaning of the FCA) that, because of their offering price concessions as a kickback, such items or units were not eligible for reimbursement, in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims. Defendants further caused such claims to be submitted for reimbursement when Defendants knew (within the meaning of the FCA) that the distribution of repackaged drug products produced by MII, which were misbranded and adulterated under the FDCA, would give rise to claims ineligible for payment.

252. Providers submitted such claims as a natural and foreseeable result of the illegal activity of Defendants described in this First Amended Complaint.

253. Defendants knowingly caused to be presented false or fraudulent claims resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

254. Government Health Care Program officials, their contractors, carriers, intermediaries, and agents, paid and approved claims for payment that should not have been paid or approved.

255. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from

officials with Government Health Care Programs, and other government officials, their contractors, carriers, intermediaries, and agents, in order to induce payment of the false and fraudulent claims.

256. Government Health Care Program officials and their contractors, carriers, intermediaries, and agents, would not have paid the claims had they known the truth.

257. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT THREE

VIOLATIONS OF FEDERAL AND STATE ANTI-KICKBACK STATUTES

258. Relator restates and realleges the allegations contained in paragraphs 1-257 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

259. Defendants have offered and paid unlawful incentives or kickbacks in violation of the AKS and comparable state anti-kickback statutes, as well as solicited and received illegal kickbacks in violation of the AKS and comparable state anti-kickback statutes. In order to sell the drugs, Defendants authorized and directed its employees and agents to offer and award unlawful incentives, and to solicit and receive kickbacks from others. These expenditures were made to doctors to influence the doctors to write prescriptions for the drug.

260. The goal of the AKS in these circumstances is to prevent the purchase or prescription of a drug based not on whether or not it is necessary and appropriate, but on whether it is financially beneficial to the doctor purchasing and/or prescribing the drug. Because of

Defendants' illegal actions, the drug has, in fact, been prescribed in violation of the AKS and the FCA.

261. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims, particularly where a provider had re-certified compliance with the Anti-Kickback Statute after having received any kickback from Defendants or otherwise.

262. Defendants caused such claims to be submitted for reimbursement when Defendants knew (within the meaning of the FCA) that, because of their offering price concessions as a kickback, such items or units were not eligible for reimbursement, in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

263. Providers submitted such claims as a natural and foreseeable result of the illegal activity of Defendants described in this First Amended Complaint.

264. Defendants knowingly caused to be presented false or fraudulent claims resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

265. Government Health Care Program officials, their contractors, carriers, intermediaries, and agents, paid and approved claims for payment that should not have been paid or approved.

266. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from officials with Government Health Care Programs, and other government officials, their

contractors, carriers, intermediaries, and agents, in order to induce payment of the false and fraudulent claims.

267. Government Health Care Program officials and their contractors, carriers, intermediaries, and agents, would not have paid the claims had they known the truth.

268. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States and the State Plaintiffs have suffered significant losses in an amount to be determined.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)

269. Relator restates and realleges the allegations contained in paragraphs 1-268 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

270. The California FCA, Cal. Gov't Code § 12651(a), specifically provides, in part:

(a) Any person who commits any of the following enumerated acts in this subdivision shall have violated this article and shall be liable to the state or to the political subdivision for three times the amount of damages that the state or political subdivision sustains because of the act of that person. A person who commits any of the following enumerated acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

(3) Conspires to commit a violation of this subdivision.

(4) Has possession, custody, or control of public property or money used or to

be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less than all of that property.

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used.

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property.

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals, or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision.

(8) Is a beneficiary of an inadvertent submission of a false claim subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

271. Defendants knowingly presented or caused to be presented to the California Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of California Government Code § 12651(a).

272. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by Defendants.

COUNT FIVE

VIOLATIONS OF THE COLORADO MEDICAID FCA
Col. Rev. Stat. § 25.5-4-305

273. Relator restates and realleges the allegations contained in paragraphs 1-272 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The Colorado Medicaid FCA, Col. Rev. Stat. § 25.5-4-305, provides and attaches liability to any person who:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;

(d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;

(f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";

(g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

274. Defendants knowingly presented or caused to be presented to the Colorado Medicaid program false or fraudulent records or statements and false or fraudulent claims for

payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the Colorado FCA.

275. The State of Colorado paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Colorado, because of these acts by Defendants.

COUNT SIX

VIOLATIONS OF THE CONNECTICUT FCA FOR MEDICAL ASSISTANCE PROGRAMS Conn. Gen. Stat. § 17b-301b

276. Relator restates and realleges the allegations contained in paragraphs 1-275 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The Connecticut FCA for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301b, provides, in part:

(a) no person shall:

(1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;

(2) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(3) Conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(4) Having possession, custody or control of property or money used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services, and intending to defraud the state or willfully to conceal the property, deliver or cause to be delivered less

property than the amount for which the person receives a certificate or receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;

(6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a medical assistance program administered by the Department of Social Services, who lawfully may not sell or pledge the property; or

(7) Knowingly make, use or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services.

277. Defendants knowingly presented or caused to be presented to the Connecticut Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the Connecticut FCA.

278. The State of Connecticut paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Connecticut, because of these acts by Defendants.

COUNT SEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)

279. Relator restates and realleges the allegations contained in paragraphs 1-278 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

280. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a), specifically provides, in part:

(a) Any person who:

(1) Knowingly presents, or causes to be presented to an officer or employee of the Government a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(4) Has possession, custody or control of property or money used or to be used by the Government and, intending to defraud the Government or willfully to conceal the property, delivers or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government who may not lawfully sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government shall be liable to the Government for a civil penalty of not less than $ 5,500 and not more than $11,000 for

each act constituting a violation of this section, plus 3 times the amount of damages which the Government sustains because of the act of that person.

281. Defendants knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Delaware Code Title 6, § 1201(a).

282. The State of Delaware paid said claims, and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by Defendants.

COUNT EIGHT

VIOLATIONS OF THE DISTRICT OF COLUMBIA FCA D.C. Code § 2-308.14(a)

283. Relator restates and realleges the allegations contained in paragraphs 1-282 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

284. The District of Columbia FCA, D.C. Code § 2-308.14(a), specifically provides, in part:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

(3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

(4) Has possession, custody, or control of public property or money used, or to be used, by the District and knowingly delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the District and knowingly makes or delivers a document that falsely represents the property used or to be used;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;

(7) Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District;

(8) Is a beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District; or

(9) Is the beneficiary of an inadvertent payment or overpayment by the District of monies not due and knowingly fails to repay the inadvertent payment or overpayment to the District.

285. Defendants knowingly presented or caused to be presented to the District of Columbia Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of D.C. Code § 2-308.14(a).

286. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by Defendants.

COUNT NINE

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)

287. Relator restates and realleges the allegations contained in paragraphs 1-286 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

288. The Florida FCA, Fla. Stat. § 68.082(2), specifically provides, in part, that:

(2) Any person who:

(a) Knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) Conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;

(d) Has possession, custody, or control of property or money used or to be used by an agency and, intending to deceive the agency or knowingly conceal the property, delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(e) Is authorized to make or deliver a document certifying receipt of property used or to be used by an agency and, intending to deceive the agency, makes or delivers the receipt without knowing that the information on the receipt is true;

(f) Knowingly buys or receives, as a pledge of an obligation or a debt, public property from an officer or employee of an agency who may not sell or pledge the property lawfully; or

(g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency, is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

289. Defendants knowingly presented or caused to be presented to the Florida

Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Florida Statute § 68.082(2).

290. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by Defendants.

COUNT TEN

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT Ga. Code Ann. § 49-4-168.1

291. Relator restates and realleges the allegations contained in paragraphs 1-290 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

292. The Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1, specifically provides, in part:

(a) Any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;

(4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

293. Defendants knowingly presented or caused to be presented to the Georgia Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Georgia Code § 49-4-168.1.

294. The State of Georgia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Georgia, because of these acts by Defendants.

COUNT ELEVEN

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21

295. Relator restates and realleges the allegations contained in paragraphs 1-294 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

296. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a), specifically provides, in part, that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(4) Has possession, custody, or control of property or money used, or to be used, by the State and, intending to defraud the State or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who may not lawfully sell or pledge the property;

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State; or

(8) Is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim;
shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due

to the act of that person.

297. Defendants knowingly presented or caused to be presented to the Hawaii Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Hawaii Revised Statute § 661-21(a).

298. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by Defendants.

COUNT TWELVE

VIOLATIONS OF THE ILLINOIS FALSE CLAIMS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)

299. Relator restates and realleges the allegations contained in paragraphs 1-298 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

300. The Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a), specifically provides, in part, that:

(1) In general, any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be

used, by the State and, knowingly delivers, or causes to be delivered, less than all the money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the State, or a member of the Guard, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state, is liable to the State for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person. The penalties in this Section are intended to be remedial rather than punitive and shall not preclude, nor shall be precluded by, a criminal prosecution for the same conduct.

301. Defendants knowingly presented or caused to be presented to the Illinois Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of 740 Illinois Compiled Statute § 175/3(a).

302. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by Defendants.

COUNT THIRTEEN

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
Ind. Code § 5-5.5-2

303. Relator restates and realleges the allegations contained in paragraphs 1-302 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

304. The Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2(b), specifically provides, in part:

(b) A person who knowingly or intentionally:

(1) presents a false claim to the state for payment or approval;

(2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

(3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;

(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

(7) conspires with another person to perform an act described in subdivisions (1) through (6); or

(8) causes or induces another person to perform an act described in subdivisions (1) through (6); is, except as provided in subsection (c), liable to the state for a civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

305. Defendants knowingly presented or caused to be presented to the Indiana Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Indiana Code § 5-11-5.5-2.

306. The State of Indiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Indiana, because of these acts by Defendants.

COUNT FOURTEEN

VIOLATIONS OF THE LOUISIANA FCA/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
La. Rev. Stat. Ann. § 46:438.3

307. Relator restates and realleges the allegations contained in paragraphs 1-306 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

308. The Louisiana FCA/Medical Assistance Programs Integrity Law ("Louisiana FCA"), Rev. Stat. Ann. § 46:438.3, specifically provides, in part, that:

A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement to obtain payment for a false or fraudulent claim from the medical assistance programs' funds.
C. No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.
D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

309. Louisiana FCA, Rev. Stat. Ann. § 46:438.2A(1), specifically provides that:

> No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or . . . payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following: (1) In return for referring an individual to a health care provider, . . . for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

310. In addition, the Louisiana FCA, Rev. Stat. Ann. § 46:438.3 provides that:

> No person shall knowingly present or cause to be presented a false or fraudulent claim . . . shall knowingly engage in misrepresentation to obtain payment from the medical assistance programs' funds . . . shall conspire to defraud, or attempt to defraud, the medical assistance programs . . . .

311. Furthermore, the Louisiana FCA, Rev. Stat. Ann. § 46:438.4, provides that:

> No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility . . . to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive.

312. Defendant knowingly presented or caused to be presented to the Louisiana Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Louisiana Revised Statute § 46:438.3.

313. The State of Louisiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Louisiana, because of these acts by Defendants.

COUNT FIFTEEN

VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT OF 2010 Md. Code Ann., Health-Gen. § 2-602

314. Relator restates and realleges the allegations contained in paragraphs 1-313 above as if each were stated herein in their entirety and said allegations are incorporated herein by

reference.

315. The Maryland False Health Claims Act, Md. Code Ann., Health-Gen. § 2-602, specifically provides that:

> (A) A person may not:
>
> (1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
>
> (2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim;
>
> (3) Conspire to commit a violation under this subtitle;
>
> (4) Have possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly deliver or cause to be delivered to the State less than all of that money or other property;
>
> (5) (i) Be authorized to make or deliver a receipt or other document certifying receipt of money or other property used or to be used by the State under a State health plan or a State health program; and
>
> (ii) Intending to defraud the State or the Department, make or deliver a receipt or document knowing that the information contained in the receipt or document is not true;
>
> (6) Knowingly buy or receive as a pledge of an obligation or debt publicly owned property from an officer, employee, or agent of a State health plan or a State health program who lawfully may not sell or pledge the property;
>
> (7) Knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State;
>
> (8) Knowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State; or
>
> (9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

316. Defendants knowingly presented or caused to be presented to the Maryland

Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the Maryland False Health Claims Act of 2010.

317. The State of Maryland paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Maryland, because of these acts by Defendants.

COUNT SIXTEEN

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws ch. 12, § 5B

318. Relator restates and realleges the allegations contained in paragraphs 1-317 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

319. The Massachusetts FCA, Mass. Gen. Laws ch. 12, § 5B, specifically provides, in part, that any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) has possession, custody, or control of property or money used, or to be used, by the commonwealth or any political subdivision thereof and knowingly delivers, or causes to be delivered to the commonwealth, less property than the amount for which the person receives a certificate or receipt with the intent to willfully conceal the property;

(5) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the commonwealth or any political subdivision thereof and with the intent of defrauding the commonwealth or any political subdivision thereof, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the commonwealth or any political subdivision thereof, knowing that said officer or employee may not lawfully sell or pledge the property;

(7) enters into an agreement, contract or understanding with one or more officials of the commonwealth or any political subdivision thereof knowing the information contained therein is false;

(8) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof; or

(9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person. A person violating sections 5B to 5O, inclusive, shall also be liable to the commonwealth or any political subdivision for the expenses of the civil action brought to recover any such penalty or damages, including without limitation reasonable attorney's fees, reasonable expert's fees and the costs of investigation, as set forth below. . . .

320. Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Massachusetts General Laws ch. 12, § 5B.

321. The Commonwealth of Massachusetts paid said claims and has sustained

damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by Defendants.

COUNT SEVENTEEN

VIOLATIONS OF THE MICHIGAN MEDICAID FCA
Mich. Comp. Laws § 400.601 *et seq.*

322. Relator restates and realleges the allegations contained in paragraphs 1-321 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

323. The Michigan Medicaid FCA, Mich. Comp. Laws § 400.603, provides, *inter alia*, that:

(1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
(2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit.
(3) A person, who having knowledge of the occurrence of an event affecting . . . [the] initial or continued right of any other person on whose behalf he has applied . . . shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

324. Section 400.606, states that "[a] person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim . . . ."

325. In section 400.607, "[a] person shall not make or present or cause to be made or presented to an employee or officer of this state a claim . . . upon or against the state, knowing the claim to be false . . . ." And that "[a] person shall not make or present or cause to be made or presented a claim . . . that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary . . . ."

326. In section 400.604, a person is prohibited from soliciting, offering, making, or receiving a kickback or bribe or rebate of any kind.

327. Under section 400.612, "[a] person who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact . . . shall forfeit and pay to the state the full amount received, and for each civil penalty of not less than $5,000.00 or more than $10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person."

328. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the Michigan Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law, knowingly made, used, or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired with others to defraud the state Medicaid program, all in violation of the Michigan FCA, and thereby caused damage to the State of Michigan.

COUNT EIGHTEEN

VIOLATIONS OF THE MINNESOTA FCA
Minn. Stat. § 15C.02(a)

329. Relator restates and realleges the allegations contained in paragraphs 1-328 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The Minnesota FCA, Minn. Stat. § 15C.02, attaches liability to:

(a) A[ny] person who . . . :

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;

(2) knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision;

(3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim;

(4) has possession, custody, or control of public property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered to the state or a political subdivision less money or property than the amount for which the person receives a receipt;

(5) is authorized to prepare or deliver a receipt for money or property used, or to be used, by the state or a political subdivision and knowingly prepares or delivers a receipt that falsely represents the money or property;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; or

(7) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or a political subdivision.

330. Defendants knowingly presented or caused to be presented to the Minnesota Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the Minnesota FCA.

331. The State of Minnesota paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Minnesota, because of these acts by Defendants.

COUNT NINETEEN

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)

332. Relator restates and realleges the allegations contained in paragraphs 1-331 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

333. The Nevada FCA, Nev. Rev. Stat. § 357.040(1), specifically provides, in part, that a person who:

> with or without specific intent to defraud, does any of the following listed acts is liable to the State or a political subdivision, whichever is affected, for three times the amount of damages sustained by the State or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $5,000 or more than $10,000 for each act:
>
> (a) Knowingly presents or causes to be presented a false claim for payment or approval.
>
> (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.
>
> (c) Conspires to defraud by obtaining allowance or payment of a false claim.
>
> (d) Has possession, custody or control of public property or money and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount for which the person receives a receipt.
>
> (e) Is authorized to prepare or deliver a receipt for money or property to be used by the State or a political subdivision and knowingly prepares or delivers a receipt that falsely represents the money or property.
>
> (f) Knowingly buys, or receives as security for an obligation, public property from a person who is not authorized to sell or pledge the property.
>
> (g) Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State or a political subdivision.
>
> (h) Is a beneficiary of an inadvertent submission of a false claim and, after

> discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

334. Defendants knowingly presented or caused to be presented to the Nevada Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Nevada Revised Statute § 357.040(1).

335. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by Defendants.

COUNT TWENTY

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

336. Relator restates and realleges the allegations contained in paragraphs 1-335 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

337. The New Hampshire FCA, N.H. Rev. Stat. Ann. § 167:61-b(I), specifically provides, in part:

> Any person shall be liable to the state for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages that the state sustains because of the act of that person, who:
>
> (a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
>
> (c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

(d) Has possession, custody, or control of property or money used, or to be used, by the department and, intending to defraud the department or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt.

(e) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the department.

(f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim.

338. Defendants knowingly presented or caused to be presented to the New Hampshire Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of New Hampshire Revised Statute § 167:61-b(I).

339. The State of New Hampshire paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New Hampshire, because of these acts by Defendants.

COUNT TWENTY-ONE

VIOLATIONS OF THE NEW JERSEY FCA
N.J. Stat. Ann. § 2A:32C-1

340. Relator restates and realleges the allegations contained in paragraphs 1-339 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3, supplementing Title 2A of the New Jersey statutes and amending New Jersey Medical Assistance and Health Services Act, P.L. 1968, c. 413, N.J. Stat. Ann. § 30:4D-17, provides in part that:

> A person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal FCA (31 U.S.C. § 3729 *et seq.*), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person commits any of the following acts:
>
> a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> c. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;
>
> d. Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;
>
> e. Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;
>
> f. Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or
>
> g. Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

341. Defendants knowingly presented or caused to be presented to the New Jersey Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the New Jersey FCA.

342. The State of New Jersey paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New Jersey, because of these acts by Defendants.

COUNT TWENTY-TWO

VIOLATIONS OF THE NEW MEXICO MEDICAID FCA
N.M. Stat. Ann. § 27-14-4

343. Relator restates and realleges the allegations contained in paragraphs 1-342 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

344. The New Mexico Medicaid FCA, N.M. Stat. Ann. § 27-14-4, specifically provides, in part, that:

> A person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains as a result of the act if the person:
>
> A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
>
> B. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
>
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;

D. conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent;

E. makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the medicaid program, knowing that such record or statement is false;

F. knowingly applies for and receives a benefit or payment on behalf of another person, except pursuant to a lawful assignment of benefits, under the medicaid program and converts that benefit or payment to his own personal use;

G. knowingly makes a false statement or misrepresentation of material fact concerning the conditions or operation of a health care facility in order that the facility may qualify for certification or recertification required by the medicaid program; or

H. knowingly makes a claim under the medicaid program for a service or product that was not provided.

345. Defendants knowingly presented or caused to be presented to the New Mexico Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired to do so, all in violation of the New Mexico Statute § 27-14-4.

346. The State of New Mexico paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New Mexico, because of these acts by Defendants.

COUNT TWENTY-THREE

VIOLATIONS OF THE NEW YORK FCA
N.Y. State Fin. Law § 189

347. Relator restates and realleges the allegations contained in paragraphs 1-346 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

348. The New York FCA, provides, in relevant part, as follows:

§ 189. Liability for certain acts.

1. Subject to the provisions of subdivision two of this section, any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of paragraph (a), (b), (d), (e), (f) or (g) of this subdivision;

(d) has possession, custody, or control of property or money used, or to be used, by the state or a local government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(e) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state or a local government and, intending to defraud the state or a local government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(f) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a local government knowing that the officer or employee violates a provision of law when selling or pledging such property; or

(g) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state

or local government sustains because of the act of that person.

349. Defendants knowingly presented or caused to be presented to the New York Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of New York State Finance Law § 189.

350. The State of New York paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New York, because of these acts by Defendants.

COUNT TWENTY-FOUR

VIOLATIONS OF THE NORTH CAROLINA FCA
N.C. Gen. Stat. § 1-607(a)

351. Relator restates and realleges the allegations contained in paragraphs 1-350 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a), attaches liability to:

Any person who . . . :

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

(3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.

(4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property.

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true.

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

352. Defendants knowingly presented or caused to be presented to the North Carolina Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the North Carolina FCA.

353. The State of North Carolina paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in North Carolina, because of these acts by Defendants.

COUNT TWENTY-FIVE

VIOLATIONS OF OKLAHOMA MEDICAID FCA
Okla. Stat. Ann. tit. 63 § 5053.1(B)

354. Relator restates and realleges the allegations contained in paragraphs 1-353 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The Oklahoma Medicaid FCA, Okla. Sta. Ann. tit. 63 § 5053.1(B), added by Laws 2007, c.137 § 63-5053.1A. 2B, provides in part that:

Any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

3. Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;

4. Has possession, custody, or control of property or money used, or to be used, by the state and, intending to defraud the state or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

6. Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, who lawfully may not sell or pledge the property; or

7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars ($5,000.00) and not more than Ten Thousand Dollars ($10,000.00), unless a penalty is imposed for the act of that person in violation of this subsection under the federal FCA for the same or a prior action, plus three times the amount of damages which the state sustains because of the act of that person.

355. Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of the Oklahoma Medicaid FCA.

356. The State of Oklahoma paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Oklahoma, because of these acts by Defendants.

COUNT TWENTY-SIX

VIOLATIONS OF RHODE ISLAND STATE FCA
R.I. Gen. Laws § 9-1.1-3(a)

357. Relator restates and realleges the allegations contained in paragraphs 1-356 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference. The Rhode Island State FCA amending Title 9 of the Rhode Island general laws entitled "Courts and Civil Procedure/Procedure Generally," ch. 9-1.1, § 9-1.1-3(a), provides, in part, that:

> Any person who:
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid;
>
> (4) has possession, custody, or control of property or money used, or to be used, by the state and, intending to defraud the state or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
>
> (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the state for

the costs of a civil action brought to recover any such penalty or damages.

358. Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Rhode Island General Law § 9-1.1-3(a).

359. The State of Rhode Island paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Rhode Island, because of these acts by Defendants.

COUNT TWENTY-SEVEN

VIOLATIONS OF THE TENNESSEE FCA
Tenn. Code Ann. § 4-18-103(a)

360. Relator restates and realleges the allegations contained in paragraphs 1-359 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

361. The Tennessee FCA, Tenn. Code Ann. § 4-18-103(a), specifically provides, in part, that any person who:

> commits any of the following acts shall be liable to the state or to the political subdivision for three (3) times the amount of damages that the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($2,500) and not more than ten thousand dollars ($10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(4) Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision;

(8) Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim; or

(9) Knowingly makes, uses, or causes to be made or used any false or fraudulent conduct, representation, or practice in order to procure anything of value directly or indirectly from the state or any political subdivision.

362. Defendants knowingly presented or caused to be presented to the Tennessee Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Tennessee Code § 4-18-103(a).

363. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by Defendants.

COUNT TWENTY-EIGHT

VIOLATIONS OF TEXAS FCA
Tex. FCA Hum. Res. Code § 32.039(b), (c)

364. Relator restates and realleges the allegations contained in paragraphs 1-363 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

365. The Texas FCA, Tex. Hum. Res. Code § 32.039, specifically provides, in part, that:

(b) A person commits a violation if the person:

(1) presents or causes to be presented to the department a claim that contains a statement or representation the person knows or should know to be false;

(1-a) engages in conduct that violates Section 102.001, Occupations Code;

(1-b) solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for referring an individual to a person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(1-c) solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;

(1-d) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(1-e) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to purchase, lease, or order, or arrange for or recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;

(1-f) provides, offers, or receives an inducement in a manner or for a purpose not otherwise prohibited by this section or *Section 102.001, Occupations Code*, to or from a person, including a recipient, provider, employee or agent of a provider, third-party vendor, or public servant, for the purpose of influencing or being influenced in a decision regarding:

(A) selection of a provider or receipt of a good or service under the medical assistance program;

(B) the use of goods or services provided under the medical assistance program; or

(C) the inclusion or exclusion of goods or services available under the medical assistance program; or

(2) is a managed care organization that contracts with the department to provide or arrange to provide health care benefits or services to individuals eligible for medical assistance and:

(A) fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract with the department;

(B) fails to provide to the department information required to be provided by law, department rule, or contractual provision;

(C) engages in a fraudulent activity in connection with the enrollment in the organization's managed care plan of an individual eligible for medical assistance or in connection with marketing the organization's services to an individual eligible for medical assistance; or

(D) engages in actions that indicate a pattern of:

(i) wrongful denial of payment for a health care benefit or service that the organization is required to provide under the contract with the department; or

(ii) wrongful delay of at least 45 days or a longer period specified in the contract with the department, not to exceed

60 days, in making payment for a health care benefit or service that the organization is required to provide under the contract with the department.

(c) A person who commits a violation under Subsection (b) is liable to the department for:

(1) the amount paid, if any, as a result of the violation and interest on that amount determined at the rate provided by law for legal judgments and accruing from the date on which the payment was made; and

(2) payment of an administrative penalty of an amount not to exceed twice the amount paid, if any, as a result of the violation, plus an amount:

(A) not less than $ 5,000 or more than $ 15,000 for each violation that results in injury to an elderly person, as defined by Section 48.002(1), a disabled person, as defined by Section 48.002(8)(A), or a person younger than 18 years of age; or

(B) not more than $ 10,000 for each violation that does not result in injury to a person described by Paragraph (A).

366. Defendants knowingly presented or caused to be presented to the Texas Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Texas FCA Human Resources Code § 32.039(b), (c).

367. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by Defendants.

COUNT TWENTY-NINE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)

368. Relator restates and realleges the allegations contained in paragraphs 1-367 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

369. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A), specifically provides, in part, that:

Any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;

2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

4. Has possession, custody, or control of property or money used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

5. Authorizes to make or deliver a document certifying receipt of property used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;

6. Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or

7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth;

shall be liable to the Commonwealth for a civil penalty of not less than $ 5,500 and not more than $ 11,000, plus three times the amount of damages sustained by the

Commonwealth.

370. Defendants knowingly presented or caused to be presented to the Virginia Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Virginia Code § 8.01-216.3(A).

371. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by Defendants.

COUNT THIRTY

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW Wis. Stat. Ann. § 20.931(2)

372. Relator restates and realleges the allegations contained in paragraphs 1-371 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

373. The Wisconsin False Claims for Medical Assistance Law, added by 2007 Wisconsin Act 20, Wis. Stat. Ann. 20.931(2), provides, in part, that:

> any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation:
>
> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> (c) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made

or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

(g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance program.

(h) Is a beneficiary of the submission of a false claim for medical assistance to any officer, employee, or agent of this state, knows that the claim is false, and fails to disclose the false claim to this state within a reasonable time after the person becomes aware that the claim is false.

374. Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid program false or fraudulent records or statements and false or fraudulent claims for payment and approval, claims which failed to disclose material violations of law, and/or concealed their actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired with others to do so, all in violation of Wisconsin Statute § 20.931(2).

375. The State of Wisconsin paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Wisconsin, because of these acts by Defendants.

CLAIMS ON BEHALF OF RELATOR PERSONALLY

COUNT THIRTY-ONE

Defendant Amgen's Unlawful Retaliation Against Relator Under 31 U.S.C. § 3730(h)

376. Relator restates and realleges the allegations in paragraphs 1-375 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

377. As set forth in detail above, after learning of Mr. Mullen's protected activities, including communicating and meeting with the Westmoreland Case lawyers, retaining undersigned counsel for his own action, debriefing the government, being deposed in the Westmoreland Case, and filing his own *Qui Tam* Action complaint, ABSG retaliated against

Mr. Mullen in December 2010 by withholding from him over $44,000 in bonus payments he was due under the terms of the severance agreement. By these actions, ABSG violated the FCA, 31 U.S.C. § 3730(h).

378. Plaintiff/Relator has been damaged as a direct result of these illegal actions. He has suffered economic harm, loss of income and future earnings, and emotional injury.

379. Defendants' conduct as alleged herein was done knowingly, maliciously, oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is entitled to recover exemplary and punitive damages against ABSG in an amount to be determined at trial.

COUNT THIRTY-TWO

Violation of the Texas FCA
Tex. Hum. Res. Code § 36.115

380. Relator restates and realleges the allegations in paragraphs 1-379 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

381. As set forth in detail above, after learning of Mr. Mullen's protected activities, including communicating and meeting with the Westmoreland Case lawyers, retaining undersigned counsel for his own action, debriefing the government, being deposed in the Westmoreland Case, and filing his own *Qui Tam* Action complaint, ABSG retaliated against Mr. Mullen in December 2010 by withholding from him over $44,000 in bonus payments he was due under the terms of the severance agreement. By these actions, ABSG violated the Texas FCA Human Resources Code § 36.115.

382. Plaintiff/Relator has been damaged as a direct result of these illegal actions. He has suffered economic harm, loss of income and future earnings, and emotional injury.

383. Defendants' conduct as alleged herein was done knowingly, maliciously,

oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is entitled to recover punitive and exemplary damages against ABSG in an amount to be determined at trial.

COUNT THIRTY-THREE

Breach of Contract

384. Relator restates and realleges the allegations in paragraphs 1-383 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

385. Pursuant to a May 10, 2010 separation agreement, ABSG agreed to provide Relator with severance compensation, comprised of the following components: a) two years of his base salary (¶ 6(b)); b) a pro-rated performance bonus under the company's Annual Incentive Plan (¶ 6(c); c) additional lump sums in cash (¶ 6(d)); and d) the cash value of certain restricted shares of company stock (¶ 6(f)).

386. ABSG has violated the terms of the separation agreement by withholding, in December 2010, over $44,000 in bonus payments that he was due under the terms of the separation agreement.

387. Accordingly, Relator is entitled to recover all damages available at law, including against ABSG, in an amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, Relator Michael Mullen, acting on behalf of and in the name of the United States of America and the State Plaintiffs, and on his own behalf, demands and prays that judgment be entered as follows against Defendants under the Federal FCA counts and under the supplemental State FCA counts and other state law counts as follows:

(a) In favor of the United States against Defendants for treble the amount of damages to Government Health Care Programs from the marketing, selling, prescribing, pricing and billing of the drugs at issue plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each violation of the FCA;

(b) In favor of the United States against Defendants for disgorgement of the profits earned by Defendants as a result of its illegal schemes;

(c) In favor of Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees, and costs incurred by Relator;

(d) For all costs of the Federal FCA civil action;

(e) In favor of Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(h), Texas FCA Hum. Res. Code § 36.115, and Texas common law due to ABSG's retaliatory actions, including double back pay with interest, front pay in lieu of reinstatement, special damages to reputation, costs, reasonable attorneys fees, and such further relief as the Court deems proper, including, without limitation, punitive damages and pre-judgment interest;

(f) In favor of Relator and the named State Plaintiffs against Defendants in an amount equal to three times the amount of damages that California, Colorado,

Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Virginia, and Wisconsin have sustained, respectively, as a result of Defendants' actions, as well as a civil penalty against Defendants of a statutory maximum for each violation of each State's FCA;

(g) In favor of Relator and the Plaintiff State of Michigan against Defendants for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of Defendants' actions, plus damages equal to three times such loss;

(h) In favor of Relator and the Plaintiff State of Texas against Defendants in an amount equal to two times the amount of damages that Texas has sustained as a result of Defendants' actions, as well as a civil penalty against Defendants of a statutory maximum for each violation of Texas FCA Human Resources Code § 36.002;

(i) In favor of Relator for the maximum amount as a relator's share allowed pursuant to each State Plaintiff's FCA;

(j) In favor of Relator for all costs and expenses associated with the supplemental state claims, including attorney's fees and costs;

(k) In favor of the State Plaintiffs and Relator for all such other relief as the Court deems just and proper; and

(m) Such other relief as this Court deems just and appropriate.

PLAINTIFFS/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

January 24, 2011

Respectfully submitted,

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