UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK *ex rel.* OMNI HEALTHCARE INC., Plaintiffs, v. MCKESSON CORPORATION, MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION, MCKESSON SPECIALTY DISTRIBUTION LLC, MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, L.P., ONCOLOGY THERAPEUTICS NETWORK CORPORATION, ONCOLOGY THERAPEUTICS NETWORK JOINT VENTURE, L.P., US ONCOLOGY, INC., and US ONCOLOGY SPECIALTY, L.P., Defendants.	Case No.: 1:12-CV-06440 (NG)

SECOND AMENDED QUI TAM COMPLAINT FOR DAMAGES

On behalf of the United States of America, the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Massachusetts, Michigan, Minnesota, Montana, Nevada, New

Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin, the District of Columbia, and the cities of Chicago and New York, Plaintiff and Relator Omni Healthcare Inc. ("Omni" or "Relator") files this *qui tam* complaint against Defendants McKesson Corporation, McKesson Specialty Care Distribution Corporation, McKesson Specialty Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Corporation, Oncology Therapeutics Network Joint Venture, L.P., US Oncology, Inc., and US Oncology Specialty, L.P. ("Defendants") under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), the False Claims Acts of the District of Columbia, states, and cities described herein, and common law theories of payment by mistake and unjust enrichment, and alleges as follows:

INTRODUCTION

1. Defendants operate one of the largest pharmaceutical distribution operations in the United States. The impact that they have on the health of millions of Americans is extraordinary. And the power that they yield as a result of their wealth and political influence is almost unfathomable.

2. This action describes unlawful business practices used by Defendants that knowingly and intentionally put cancer patients and others with compromised immune systems at serious risk for infection, and defrauded federal, state, and local governments out of hundreds of millions of dollars.

3. When Defendants' primary competitor engaged *in this very same conduct*, it led to a criminal indictment and a subsequent criminal guilty plea with fines and penalties together with an announced civil settlement in principle of nearly one billion dollars.

4. Some of the most senior Government officials charged with ensuring the health and safety of Americans recently publicized their concerns that Defendants are above the law—that they have harmed and will continue to harm millions of Americans, for profit, and with impunity.[1]

5. As evident in this action, Defendants continue to elect corporate revenue over patient safety. This civil action seeks to hold Defendants responsible for their fraudulent and harmful behavior.

NATURE OF THE ALLEGATIONS

6. This action arises from Defendants' unlawful conduct in connection with their manufacture, distribution, and sale of various injectable oncology, anemia, and related drugs in pre-filled syringes for administration to cancer patients undergoing chemotherapy treatment as well as other immuno-compromised patients (the "Pre-Filled Syringe Program"). The drugs at issue include Aloxi®, Procrit®, Aranesp®, Neupogen®, Taxotere®, and Kytril® (in both brand and generic forms) (the "Oncology Drugs"), which all contained significant amounts of overfill. Combined, Defendants engaged in their unlawful conduct from 2001 until at least 2010, and engaged in this conduct with respect to Relator from 2007 through 2010.

[1] McKesson Corporation's ("McKesson") systemic disregard for the legal system in ways directly implicating patient health has been recently highlighted by its role in what David Schiller, the leader of the United States Drug Enforcement Administration ("DEA") team investigating the opioid crisis, called the "best case we've ever had against a major distributor." Schiller, along with other Government officials, expressed outrage that McKesson was not held accountable for providing millions of dangerous pills, failing to flag *any* suspicious orders, and not maintaining due diligence even after its actions were discovered. As stated by Mr. Schiller: "They're killing people. And their motive? This is all for financial gain." According to the report, notwithstanding a long investigation, the DEA attorneys were "intimidated," and McKesson received special treatment beyond what Schiller had seen "in his thirty years." Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy On McKesson, The Country's Largest Distributor*, CBS NEWS (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor.

7. Specifically, and as described in greater detail below, Defendants repackaged or compounded the Oncology Drugs in an unlawful manner that was unapproved by the United States Food and Drug Administration ("FDA") and in non-sterile conditions, resulting in false claims being submitted (i) for drugs that were unapproved by the FDA; (ii) for adulterated and misbranded drugs that were repackaged or compounded in a manner in which they could become compromised, lacking purity, and generally below the standards they were represented or expected to possess by the governments; (iii) for improperly harvesting overfill, such that the governments were billed improperly for drug product that was not covered for reimbursement; (iv) for improperly harvesting overfill and charging for that overfill, along with the original drug product, in pre-filled syringes when the overfill in question was not used to calculate the Average Sales Price ("ASP"), causing the governments to pay artificially inflated prices for the drug product; and (v) for Oncology Drugs purchased as a result of Defendants' unlawful kickback to physicians for purchasing pre-filled syringes.

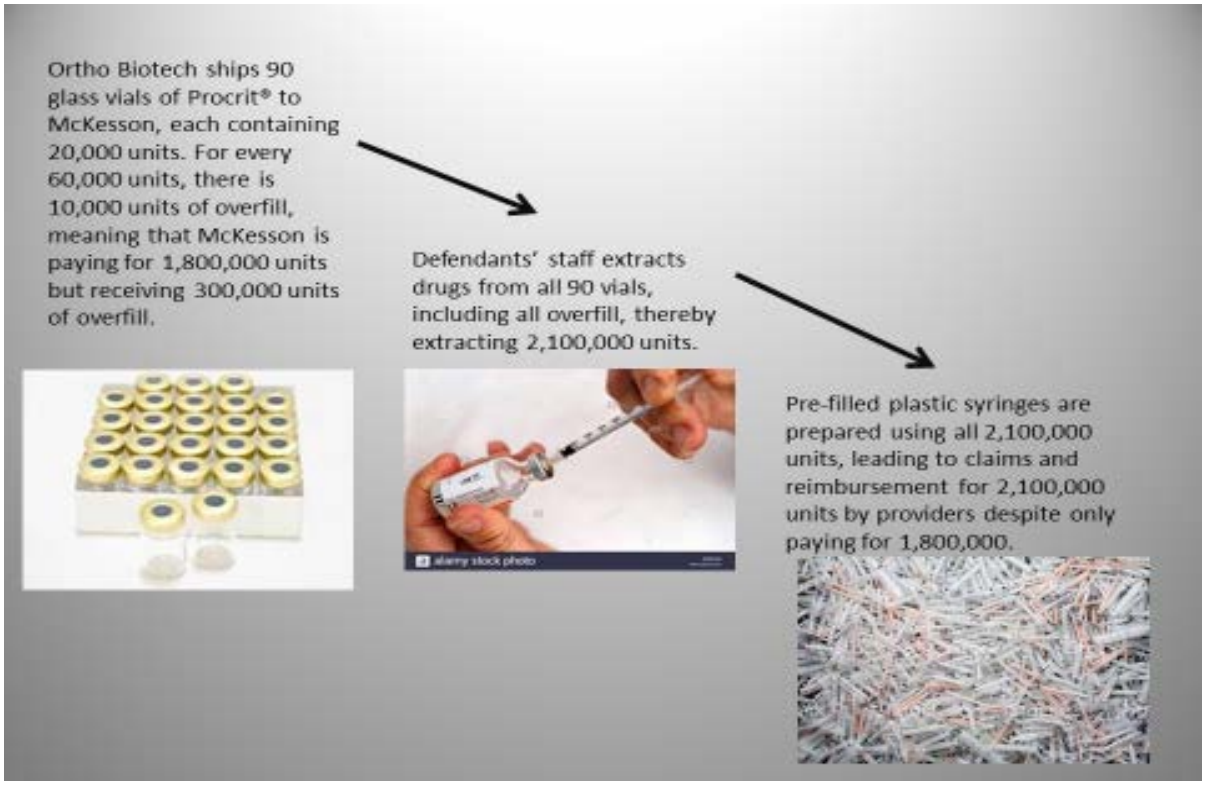
8. To ensure that a doctor is able to withdraw the full amount of a drug sold in an FDA-approved container, typically a glass vial, the containers holding the Oncology Drugs contain more of the product than the amount indicated on the label. This excess amount is called "overfill." Providers are not allowed to bill for any excess drug, such as overfill, for which the drug manufacturer does not charge. Nor are they allowed to bill for unapproved drugs, such as those repackaged in unapproved facilities or otherwise in violation of FDA guidelines.

9. Moreover, most of these vials are expressly marked for "single use," *i.e.*, the contents may be extracted only once because they do not contain preservatives or antiseptic chemicals to prevent bacterial or fungal growth.

10. Nonetheless, Defendants learned that they could maximize profits at the governments' expense by harvesting overfill in covered drug products such as the Oncology

Drugs, pooling the Oncology Drugs, and then repackaging them in bulk into non-sterile and plastic pre-filled syringes, despite the clear risk to vulnerable cancer patients.

11. Defendants would sell the pre-filled syringes to oncology centers, medical practices, and physicians (collectively, "healthcare providers"), who, in turn, would seek reimbursement for amounts sold in the government-approved vials and quantities. As a result, the governments were billed for an amount of drug product in the pre-filled syringes greater than the amount of vials originally sold by the drug manufacturers, thus allowing Defendants or the healthcare providers to obtain government funds for drugs that were never, in fact, charged for by the drug manufacturers. The following is a simple illustration of this scheme:



12. In the case of US Oncology, Inc. and US Oncology Specialty, L.P. ("US Oncology"), US Oncology would also bill the governments directly for those syringes and overfill.

13. Defendants' profit motive bolstered them to, through the Pre-Filled Syringe Program, expose the previously sterile drugs to contamination through unclean environments, unsafe practices, and the improper use of plastic syringes for storage and shipment under conditions that did not ensure the sterility and potency of the products, and which failed to comply with FDA and other government requirements.

14. To begin with, by their unlawful activities, Defendants manufactured unapproved new drugs. All vials of the Oncology Drugs are either drugs under 21 U.S.C. § 321(g)(1), or biological drug products under 42 U.S.C. § 262(i). Additionally, the FDA has not even approved the administration of Procrit®, Aloxi®, Kytril®, or Taxotere® in pre-filled syringes.

15. However, Defendants never submitted New Drug Applications ("NDA") or Biologics License Applications ("BLA") for the repackaged Oncology Drugs.

16. Defendants did not, adequately or at all, submit any safety, stability, or sterility data gathered from their Pre-Filled Syringe Program to the FDA, nor did they repackage the drugs in a way that would guarantee the Oncology Drugs' safety and efficacy.

17. Rather, Defendants manufactured and repackaged the Oncology Drugs in a proven unsafe fashion and under demonstrably non-sterile conditions. In doing so, Defendants violated virtually all requirements that the Government requires companies to meet in manufacturing, processing, labeling, packing, and holding of drugs and biologics to ensure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess.

18. Additionally, the pre-filled syringes that Defendants created were repackaged or compounded in a manner inconsistent with FDA standards, causing the products to become adulterated and misbranded.

19. Contrary to well-known laws, rules, regulations, and medical knowledge, in facilities in at least Frisco, Texas (later moved to Memphis, Tennessee), as witnessed firsthand by Omni's principal on or about August 28, 2007 during a meeting—in which Omni's principal met with approximately six individuals at OTN, including the Vice President of Payer Sales, the National Vice President of Sales, and the President of OTN Specialty Services, among others—Defendants pooled overfill from the FDA-approved packages of the Oncology Drugs in non-aseptic facilities, with workers in non-aseptic clothing/gear, in a fashion that created adulterated products placed into plastic pre-filled syringes, which in turn were then re-labeled (in some instances with fake product codes and expiration dates), then packaged and shipped in violation of FDA and drug-specific requirements. The net result of the altered expiration dates was that sterile drugs, mostly preservative-free, were exposed to conditions that could lead to contamination, placed in plastic syringes that were not designed for extended storage, and then given a shelf life beyond that contemplated by the manufacturers. Additionally, there is no information to suggest that Defendants properly tested the sterility and stability of the repackaged drug product after repackaging.

20. The pooling of the Oncology Drugs into these syringes also made it difficult to trace the precise origins of the drug in the syringe back to its correct manufacturer batch and lot (a drug's "Pedigree")—something that is necessary for health officials in the event of contamination or other issues with the medication. In addition, Defendants focused their Pre-Filled Syringe Program on Oncology Drugs that are administered to patients already prone to infection to increase their chances of their unlawful conduct going undetected. Defendants presumably assumed that any infections and resulting patient deaths would likely be falsely attributed to the patients' disease and treatment, as opposed to healthcare providers' unwittingly administering non-sterile and unapproved drugs.

21. Furthermore, Defendants manufactured the pre-filled syringes in response to order forms that they themselves submitted to physicians, and which did not provide space for individual patient names or prescriptions. Instead, the syringes were mass-produced. None of Defendants' facilities had been authorized by the FDA to perform such wholesale repackaging, nor is this permitted by the FDA. As such, and without a license to do so, Defendants manufactured or caused to be manufactured drugs in facilities not approved for these activities by the FDA.

22. Defendants knowingly engaged in the aforementioned unsafe illegal practices because of the significant profit gains resulting therefrom. By utilizing the overfill from the vials of the Oncology Drugs, Defendants were able to manufacture more "vials" in the form of pre-filled syringes than were provided to them by the original manufacturers; therefore, even at the discounted price offered to providers for the pre-filled syringes, Defendants were able to charge more than they would have otherwise been able to had they simply distributed the vials. This caused the governments to reimburse for excess amounts, which the governments would not have paid had they been aware of the conduct alleged herein.

23. But the effects of Defendants' Pre-Filled Syringe Program extend beyond fraudulently induced reimbursements for Defendants' pre-filled syringes. The program artificially inflated the ASP used by the Government to determine reimbursement rates for the Oncology Drugs – including those used for all reimbursements for lawful sales of the drugs in their original manufacturer packaging – by introducing into commerce drug product specifically excluded from the calculation of the ASP, namely, overfill, and failing to report the lower prices that Defendants charged for drug product in pre-filled syringes, as opposed to the same drug product sold in glass vials. This created a situation wherein federal, state, and local governments overpaid for each reimbursement on these drugs.

24. Finally, Defendants induced healthcare providers to purchase the pre-filled syringes as opposed to the vials by offering a discount for the pre-filled syringes. In this way, Defendants offered illegal kickbacks to the healthcare providers, made possible vis-à-vis the essentially "free" overfill drugs for which they had not paid the manufacturers, in violation of the Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1328-7d (the "AKS"), which prohibits any person or entity from knowingly or 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 part by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b), (f).

25. Indeed, Defendants promoted the discounted pricing offered for drugs in pre-filled syringes. Defendants stated that they were providing the pre-filled syringes because they could harvest overfill more effectively than healthcare providers and because it would be inconvenient for healthcare providers to harvest overfill themselves.

26. At all times, Defendants knew that their conduct was illegal or, at the very least, Defendants acted in reckless disregard of the law and patient safety, for the sole purpose of increasing profitability and market share. Indeed, with full knowledge of the dangerous and illegal nature of this practice, McKesson spent several years and billions of dollars to acquire two groups of companies that enabled it to cast its net wider – Oncology Therapeutics Network Corporation and US Oncology Holdings, Inc. – forming an entire business division at McKesson.

27. As a result of the actions outlined above, and as described in greater detail below, Defendants caused false claims for reimbursement to be submitted to and honored by the United States, the District of Columbia, numerous states, and cities – claims that would not have been paid had these governments known of Defendants' improper and unsafe practices. Defendants further, through US Oncology, actually submitted claims for reimbursement on behalf of

affiliated physicians as part of their provided services. By commercially repackaging the drugs, distributing adulterated and misbranded drugs, and by manufacturing unapproved drugs, Defendants' conduct caused healthcare providers to submit claims to federal, state, and local government-funded health care programs for reimbursement of injectable oncology drugs that were false and fraudulent, and further rendered their own claims submitted false and fraudulent.

28. The false or fraudulent claims and statements at issue involve payments for prescription drugs made by: (i) federal government-funded health assistance programs, including to the Medicare Program, Title XVII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"), and the Medicaid Program, 42 U.S.C. §§ 1396-1396v ("Medicaid"); and (ii) direct federal government purchases, including payments made by the United States Department of Defense ("DOD") under the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"), and the United States Department of Veterans Affairs ("VA"), Veterans Health Administration, 38 U.S.C. Chapter 17. The false or fraudulent claims and statements at issue also involve payments made by state or local government-funded health assistance programs, including Medicaid, and payments made by other state or local government-funded agencies or entities.

29. This is an action to recover treble damages and civil penalties on behalf of the United States of America, the District of Columbia, states, and cities in connection with Defendants' violations of the FCA and the False Claims Acts of the District of Columbia and the specified states and cities, as well as under common law theories of payment by mistake and unjust enrichment. Like its equivalent local statutes, the FCA provides, *inter alia*, that any person who knowingly presents and/or causes to be presented to the United States a false or fraudulent claim for payment is liable for a civil penalty of up to $10,000 for each claim submitted, plus three times the amount of the damages sustained by the Government. 31

U.S.C. § 3729. The FCA also allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. 31 U.S.C. § 3730.

JURISDICTION AND VENUE

30. This Court has jurisdiction pursuant to 31 U.S.C. § 3732 and concurrent jurisdiction over state law claims because those claims arise from the same transaction or occurrence giving rise to the claims brought under the FCA.

31. Additionally, pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the FCA. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the remaining claims on the grounds that those claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

32. At all relevant times, Defendants regularly conducted substantial business within the state of New York, maintained permanent employees in the state of New York, and made, and are making, significant sales and claims for reimbursement in the state of New York, within this judicial district.

33. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), which provides that any action brought under § 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant, can be found, resides, transacts business, or in which any act proscribed by § 3729 occurred. The acts complained of herein occurred in the state of New York within this judicial district, as well as nationwide. Additionally, venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1)-(2).

FILING UNDER SEAL

34. Under the FCA, as well as the False Claims Acts of the District of Columbia, states, and cities, pleadings are to be filed *in camera* and remain under seal for a period of at least sixty (60) days and shall not be served on Defendants until the Court so orders. The Government has reviewed Relator's Second Amended Complaint and does not object to the lifting of the seal so as to allow the public filing of this pleading.

35. As required by 31 U.S.C. § 3730(b)(2), Relator voluntarily submitted prior to the filing of the First Amended Complaint a confidential written disclosure statement (subject to the attorney-client privilege) to the United States Government, containing materials, evidence, and information in its possession pertaining to the allegations contained in the First Amended Complaint. Relator also voluntarily submitted a confidential written disclosure statement and the First Amended Complaint to the District of Columbia, as well as the states and cities under whose FCAs this action is partially brought.

PARTIES

36. Relator Omni Healthcare, Inc. is a professional medical company primarily based in Brevard County, Florida. It serves patients in the practice of hematology/oncology throughout east central Florida. It practices through physicians in central Florida and specializes in the field of internal medicine with a subspecialty in hematology and oncology. Omni, through its principals, regularly treats cancer patients on both an inpatient and outpatient basis and regularly purchases drugs from various distributors and wholesalers to treat its patients for both the underlying disease condition, as well as for the other conditions associated with cancer and attendant side effects.

37. Relator is the original source of the facts and information hereinafter set forth concerning the activities of the Defendants relative to the manufacture, adulteration,

misbranding, promotion, and sale of the pre-filled syringes being manufactured, adulterated, mislabeled, promoted, and sold by Defendants, which are then improperly being billed to Medicare, the states' Medicaid Programs, and other federal, state, and city reimbursement programs. The facts averred herein are based upon the personal observation of Omni's principal, and documents and information in his possession, which were acquired by him in connection with his work as an oncologist treating patients with cancer using Defendants' drugs. This includes, but is not limited to, information gathered during the principal's visits to the facilities in which the unlawful practices were perpetrated, as well as the principal's own conversations with Defendants' employees which, in turn, prompted Relator to question Defendants' behavior.

38. Defendant McKesson is a Delaware corporation headquartered in San Francisco, California and is publicly traded on the New York Stock Exchange under the symbol "MCK." McKesson is one of the largest pharmaceutical distributors in North America, with approximately $192.5 billion in revenue in the 2017 fiscal year alone. One-third of all pharmaceuticals used every day in North America are delivered by McKesson, and McKesson supplies more than 40,000 United States healthcare locations including physicians, retail pharmacies, long-term care sites, hospitals, medical-surgical manufacturers, homecare agencies, health care payers, and pharmaceutical manufacturers. In 2010, McKesson's net revenue from its Distribution Solutions business segment was $105.6 billion out of a total $108.7 billion in revenue. McKesson operates multiple business divisions, including McKesson Specialty Health, f/k/a McKesson Specialty Care Solutions.[2]

[2] During the relevant time period, McKesson Specialty Care Solutions focused on delivery of complex medications, such as oncology products, across multiple delivery channels (*e.g.*, direct-to-physician wholesale, patient-direct specialty pharmacy dispensing, and access to retail pharmacy), through its distribution services, and also offered reimbursement, data collection, and analysis services. McKesson Specialty Health currently has locations in The Woodlands and Ft. Worth, Texas; Scottsdale, Arizona; San Francisco and South San Francisco, California; Overland Park, Kansas; La Vergne, Tennessee, which includes its specialty distribution center; and other

39. Defendant McKesson Specialty Care Distribution Corporation ("McKesson Specialty"), a subsidiary of McKesson Corporation, is incorporated under the laws of the state of Delaware and headquartered in San Francisco, California. McKesson Specialty is a healthcare services company that distributes medical supplies and pharmaceutical products to the healthcare industry, including to specialty medical providers like oncology practices. McKesson Specialty currently has a distribution center and principal place of business in La Vergne, Tennessee. McKesson Specialty is the successor to McKesson Specialty Care Distribution Joint Venture, L.P., an agent for McKesson.

40. Defendant McKesson Specialty Distribution LLC is a limited liability company that was incorporated under the laws of the state of Delaware in 2004 and is headquartered in San Francisco, California. McKesson Specialty Distribution LLC is a wholly-owned subsidiary of McKesson.

41. Defendant McKesson Specialty Care Distribution Joint Venture, L.P., a subsidiary of McKesson, is a Delaware limited partnership with its principal place of business in San Francisco, California. McKesson Specialty Care Distribution Joint Venture, L.P. was formerly known as and is the successor-in-interest to Oncology Therapeutics Network Joint Venture, L.P., and was itself succeeded by McKesson Specialty. Among other things, Defendant McKesson Specialty Care Distribution Joint Venture, L.P. created accounts with, and issued order forms to, healthcare providers to place orders through Defendants' Pre-Filled Syringe Program. Relator has placed orders for Oncology Drugs with, and has received invoices from, McKesson Specialty Care Distribution Joint Venture, L.P. via its distribution

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distribution center operations located in Sacramento, California and Memphis, Tennessee. Relator understands that McKesson Specialty Care Distribution Joint Venture, L.P., f/k/a Oncology Therapeutics Network Joint Venture, L.P., was part of the business of McKesson Specialty Care Solutions during the relevant time period.

center and office located at 401 Mason Road, La Vergne, Tennessee. Since 2007, McKesson Specialty Care Distribution Joint Venture, L.P. has also been a government contractor, selling drugs and biologics directly to the VA.

42. At all relevant times, Defendant Oncology Therapeutics Network Corporation ("OTN") was incorporated under the laws of the state of Delaware, with headquarters in San Francisco, California, and acted as a general partner of Oncology Therapeutics Network Joint Venture, L.P. Formed in 1993, OTN was one of the first distributors to create a specialty niche market for servicing community-based oncology practices. On October 29, 2007, McKesson acquired all outstanding shares of OTN, along with its subsidiaries, for approximately $519 million. McKesson thereafter integrated OTN with its business McKesson Specialty Care Solutions, later renamed McKesson Specialty Health. At the time of the acquisition, OTN was one of the largest distributors of specialty pharmaceutical products, including oncology drugs, in the United States, serving more than 3,500 oncologists, 1,500 rheumatologists, and other providers. Its annualized revenues were approximately $3 billion. As a result of the OTN acquisition, McKesson became the second largest specialty pharmaceutical distributor in the United States.

43. Defendant Oncology Therapeutics Network Joint Venture, L.P. was a Delaware limited partnership with its principal place of business in San Francisco, California. Defendant OTN was the general partner of Defendant Oncology Therapeutics Network Joint Venture, L.P. Relator has placed orders for Oncology Drugs with, and has received invoices from, Oncology Therapeutics Network Joint Venture, L.P. via its distribution center and office located at 401 Mason Road, La Vergne, Tennessee. Defendant Oncology Therapeutics Network Joint Venture, L.P. was acquired by Defendant McKesson on October 29, 2007.

44. Defendant US Oncology, Inc. is a corporation incorporated under the laws of the state of Delaware with its principal place of business in The Woodlands, Texas. US Oncology, Inc. is wholly-owned by US Oncology Holdings, Inc. In December 2010, McKesson purchased US Oncology Holdings, Inc., along with its subsidiaries. US Oncology, Inc. is now a wholly-owned subsidiary of McKesson operating in the McKesson Specialty Health division.

45. Relevant to this action, according to US Oncology, Inc., the company "helps expand and improve patient access to high quality, integrated and advanced cancer care by working closely with physicians, pharmaceutical manufacturers and payers to improve the safety, efficiency and effectiveness of the cancer care delivery system" and "provides drug distribution and specialty pharmacy services" that "aim to increase patient access to pharmaceuticals through a safe and efficient delivery system." US Oncology, Inc. and its subsidiaries "provide extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced cancer care treatments, build integrated community-based cancer care centers, improve their therapeutic drug management programs, and participate in cancer-related clinical research studies. US Oncology, Inc. also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis." According to US Oncology, Inc.: "Because of the significant size and scale of our network, we negotiate all pharmaceutical purchases directly with drug manufacturers and are generally able to procure market-differentiated pricing. In addition, we work with affiliated practices to implement efficient operating processes to manage inventory, eliminate waste and enhance product safety."

46. Defendant US Oncology Specialty, L.P. is a limited partnership launched by US Oncology, Inc. and incorporated under the laws of the state of Delaware in 2005. At that time, US Oncology Specialty, L.P. was "a specialty pharmaceutical distribution business to facilitate

the flow of oncology pharmaceuticals from the pharmaceutical manufacturers to their network of over 1,400 oncologists nationwide." US Oncology Specialty, L.P. currently operates as a subsidiary of McKesson.

47. From at least 2005 through and after the time of its acquisition by McKesson, US Oncology provided oncologists with pharmaceutical distribution services described as:

> Our distribution center increases the safety of drugs through a state-of-the-art e-Pedigree technology that tracks drug therapies from the manufacturer to the practice, ensuring that drugs administered to patients by our affiliated physicians are genuine and unadulterated. Located in Fort Worth, Texas, our distribution center supplied approximately 95% of the value of pharmaceuticals administered by our network of affiliated practices in 2009.

48. At the time of its acquisition by McKesson, US Oncology and its subsidiaries distributed 2.4 billion dollars-worth of oncology pharmaceuticals annually and operated eighty three comprehensive cancer centers. It was affiliated with 1,400 physicians operating in over 400 locations, including 99 radiation oncology facilities in 39 states that treated over 900,000 patients annually. In addition, governmental programs, such as Medicare and Medicaid, were collectively the affiliated practices' largest payers. At the time of its acquisition by McKesson, US Oncology and its subsidiaries represented approximately sixteen percent of the oncology market in the United States.

49. "For the three months ended September 30, 2010 and 2009, the affiliated practices under comprehensive service agreements derived 41.2% and 39.6%, respectively, of their net patient revenue from services provided under the Medicare program (of which 7.6% and 7.2%, respectively, relate to Medicare managed care) and 4.2% and 3.8%, respectively, from services provided under state Medicaid programs."

ALLEGATIONS

I. GENERAL ALLEGATIONS

A. General Description of Pharmaceutical Industry Chain of Distribution

50. In the broadest terms, in the United States, prescription drugs (pharmaceuticals) and biologics are manufactured by drug manufacturers. Most drug manufacturers manufacture either brand name drugs or generic drugs, but some manufacture both. The manufacturer places the drug into the legally-approved container, labels the drugs with all of the information and data required by the governing laws and regulations, labels the drugs with pedigree information such as lot numbers so that anyone receiving the drug down chain can identify its exact date and location of manufacture, and packages the drugs for distribution in government-approved packaging.

51. Wholesale distributors then purchase the drugs from the manufacturers and provide the operational infrastructure necessary to distribute the drugs further, such as warehouse facilities, distribution vehicles, and inventory control systems.

52. Wholesale distributors generally deliver the drug products to pharmacies who, in turn, distribute the drugs to physicians or directly to the consumers. Wholesale distributors can also distribute drug products directly to healthcare providers. Certain pharmacies purchase drug products directly from the manufacturer. There are also specialty pharmacies or distributors that specialize in the distribution of more expensive, complex drug products, such as self-injectable drugs and biologics.

53. Defendants are wholesale distributors and specialty pharmacies in the oncology industry.

54. Once Defendants here provided the Oncology Drugs to healthcare providers, the healthcare providers would then administer the Oncology Drugs to the patients and seek

reimbursement from the federal, state, and city healthcare programs described below. On behalf of its physicians, US Oncology would further submit its own claims for reimbursement from the federal, state, and city healthcare programs described below.

B. Impacted Government-Funded Programs

55. Medicaid is the nation's medical assistance program for the needy and medically-needy aged, blind, and disabled in families with dependent children. *See* 42 U.S.C. §§ 1396-1396v. Medicaid is largely administered by the states and funded by a combination of federal and state funds. Approximately fifty-seven percent of Medicaid funding is provided by the federal government on a national basis. Among other forms of medical assistance, the Medicaid programs cover outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(12). Medicaid also institutes the Medicaid Managed Care program, which provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and managed care organizations, such that those states can reduce Medicaid program costs and better manage utilization of health services.

56. With respect to state-administered Medicaid Programs, the federal government broadly institutes certain requirements for coverage and establishes baseline levels for eligibility. For example, California's Medicaid Program, Medi-Cal, is jointly financed by the federal and state governments, and provides healthcare to low-income residents. The named States and District of Columbia have various iterations of this program, including Colorado (Health First Colorado); Connecticut (HUSKY Health); Delaware; Florida; Georgia; Hawaii (MED-QUEST); Illinois; Indiana; Iowa; Louisiana; Maryland; Massachusetts (MassHealth); Michigan; Minnesota; Montana; Nevada; New Hampshire; New Jersey; New Mexico (named Centennial Care beginning January 1, 2014); New York; North Carolina; Oklahoma (SoonerCare); Rhode

Island; Tennessee (TennCare); Texas; Vermont (Green Mountain Care); Virginia; Washington (Apple Health); and Wisconsin (Badger Care).

57. Medicare is the nation's health program for persons over sixty-five years of age and persons who are disabled. Medicare is funded by the federal government. Medicare Part B has long covered outpatient prescription drugs that are provided to a patient "incident to" a physician's services, including injectable medications and drugs that are required for the effective use of durable medical equipment. 42 U.S.C. § 1395x(s)(2)(A). Commencing on January 1, 2006, Medicare Part D provided comprehensive outpatient prescription drug coverage for brand name and generic drugs according to National and Local Coverage Determinations. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003). Medicare also provides a type of health plan called a Medicare Advantage Plan, in which Medicare contracts with a private company to provide Part A and Part B benefits.

58. The VA provides medical assistance, including prescription drug coverage, to persons who have been discharged from active duty service in the military, naval, or air services.

59. The United States Public Health Service ("PHS") provides funding, including outpatient drug coverage, for entities such as black lung clinics, AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate share hospitals, and other entities listed in § 340B(a)(4) of the Public Health Service Act, 42 U.S.C. § 201 *et seq.*

60. The DOD administers the TRICARE health care program for active duty and retired members of the uniformed services, their families, and survivors. TRICARE benefits include comprehensive prescription drug coverage.

61. The Children's Health Insurance Program ("CHIP") provides low-cost health coverage to children in families with income exceeding eligibility for Medicaid. All states offer CHIP coverage, with some states also providing coverage for pregnant women.

C. The Anti-Kickback Statute

62. The AKS arose out of congressional concern that the remuneration and gifts given to those who influence health care decisions corrupts the medical decision-making process and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs, Congress enacted the AKS 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 Medicare and the Medicaid Programs." H.R. Rep. No. 92-231 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

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

64. The AKS not only prohibits outright bribes and rebate schemes, but also prohibits any payment to a physician that has, as one of its purposes, inducement of the physician to write prescriptions for a particular product.

65. Compliance with the AKS is a precondition to participation as a healthcare provider under the federally-funded health care programs and the state Medicaid programs.

D. Pharmaceutical Safety Regulation

1. The FDA Regulatory Process is Designed to Ensure the Safety and Efficacy of Drug Products Consumed by Americans through a Combination of Pre-Approval, Inspection, and Enforcement

66. The FDA is an agency within the U.S. Department of Health and Human Services ("HHS") responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers, *inter alia*, the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

67. To assist in the understanding the administration and enforcement of the FDCA, the FDA publishes regulations relating to the approval, manufacture, labeling, and distribution of drugs and biologics.

a. *Approval Process For Drugs*

68. Before a new drug may be legally marketed in the United States, it must be approved by the FDA as safe and effective for its intended use. According to the FDA, drugs lacking this approval may pose a significant public health concern because they may not meet the FDA's standards for safety, effectiveness, quality, and labeling. The sponsor of a new drug makes a formal application to the FDA to approve the new drug for use in the United States by submitting a New Drug Application ("NDA") under 21 U.S.C. § 355(b)(1) or a Biologics License Application ("BLA") under 42 U.S.C. § 262(a).[3]

69. An NDA must include: (i) a full list of the articles used as components of such drug; (ii) a full statement of the composition of such drug; and (iii) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and

[3] Manufacturers of generic drugs must also seek FDA approval for their products prior to marketing and must meet certain requirements regarding the manufacturing, labeling, and the container in which product is sold. *See, e.g.*, 21 C.F.R. § 314.94.

packing of such drug. 21 U.S.C. § 355(b)(1)(B)–(D). The NDA must also include results and analyses from tests of the drug on both animals and humans. In essence, the NDA must provide sufficient information to allow FDA reviewers to make several critical decisions, and, for a drug to be approved, the results of the study must show that the drug is safe and effective, and that its benefits outweigh its risks.

70. Approval is therefore based on, among other things, the processes, facilities, and controls used in the manufacture of the product. This is because various aspects of the manufacturing process, including "sterilization, mixing, filling, and packaging, can have a significant effect on safety and efficacy of a drug product." Food and Drug Administration, Compliance Policy Guide ("CPG") § 446.100 (issued Jan. 18, 1991).

71. The FDA also reviews a new drug's labeling information and container closure system as part of an NDA. *See* 21 C.F.R. § 314.50 (c)(2)(1) and (d)(1)(ii); *see also* 21 C.F.R. § 601.2(a) (describing information required for a BLA submission, including specimens of labels, closures, and containers).

72. Once a product has been approved for marketing, the FDA requires that manufacturers obtain FDA approval for, or make the FDA aware of, changes in the conditions established in an approved application. *See* 21 C.F.R. §§ 314.70 and 314.81; *see also* 21 C.F.R. § 601.12.

73. Major changes to drugs post-FDA approval, which have substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product, require advance submission of a supplement to the FDA and approval by the FDA. 21 C.F.R. § 314.70. Such changes include changes to a product container closure system that controls the drug product

delivered to a patient or changes in the type or composition of a packing component, including from vials to syringes. *Id.* § 314.70(b)(2)(iv); *see also id.* § 601.12(a)(2).

b. *Regulation of Drug Manufacturing*.

74. With regard to pharmaceutical quality and manufacturing standards, the FDA publishes Current Good Manufacturing Practices ("CGMPs"). These regulations set forth the minimum requirements that companies must meet in manufacturing, processing, packing, and holding drugs to ensure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess. The relevant CGMPs are codified in 21 C.F.R. parts 210 and 211.[4]

75. The CGMPs dictate, *inter alia*, standards for: personnel engaged in quality control; the design, construction, and maintenance of buildings and facilities; the construction, cleaning, and maintenance of equipment; the storage, inspection, and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage, and distribution; laboratory controls, including testing of drug product batches for conformity with final specifications; maintenance of records and reports and conduct of investigations; and procedures for handling of returned and salvaged product.

76. Manufacturers demonstrate compliance with CGMPs through written documentation of procedures and practices that are reviewed by the FDA during inspections.

[4] At the same time, states generally regulate the practice of pharmacy. For example, under the Alabama Pharmacy Practice Act, Ala. Code § 34-23-1 *et seq.*, the practice of pharmacy is "declared to affect the public health, safety, and welfare of the people of Alabama" and is "declared to be a matter of the public interest and concern that only qualified persons compound or dispense prescription drugs and medicines, and that pharmacies be managed in such a manner as to protect the public." *Id.* § 34-23-2.

77. Drugs are deemed to be adulterated if they are not manufactured in compliance with the CGMPs, if their strength differs from, or if their quality or purity fall below, the requisite standards, or if they are contaminated. 21 U.S.C. § 351(a)(2)(A)(B). It is a violation of the FDCA, 21 U.S.C. § 331(a), to directly or indirectly cause adulterated drugs to be introduced or delivered for introduction into interstate commerce.

78. FDA requires that companies engaging in the repackaging of a pharmaceutical register with FDA. *See* 21 U.S.C. § 360(a). Repackaged drugs are generally subject to the premarket approval, misbranding, and adulteration provisions of the FDCA, including new drug applications, adequate directions for use, and CGMPs. 21 U.S.C. §§ 355, 352(f)(1), and 351(a)(2)(B).

79. The lawful compounding of drugs is the practice wherein a licensed pharmacist, licensed physician, or a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

80. Each step in the manufacture and processing of a new drug must be approved by the FDA, whether carried out by the original manufacturer or by a subsequent handler or repacker of the product. *See* CPG § 446.100.

81. The FDA has noted its concerns about the manipulation of approved sterile products, especially when the sterile container is opened or otherwise entered to conduct manipulations. *Id.* When repackagers manipulate drug products beyond the intended uses approved in the labeling, this results "in new products whose safety and effectiveness have not been established. . . . Repacking by a new manufacturer may result in an unanticipated interaction between the pharmaceutical entity and the new packaging, such as absorption and degradation, which may affect the quality and purity of the product." *Id.* The FDA has noted that "[t]he moment a sterile container is opened and manipulated, a quality standard (sterility) is

destroyed and previous studies supporting the standard(s) are compromised and are no longer valid." *Id.*

82. Pharmacists are not exempt, and the FDA regards any manipulations of approved drugs by licensed pharmacists, "*consistent with the approved labeling of the product*, as an approved use of the product" only "if conducted within the practice of pharmacy, i.e., *filling prescriptions for identified patients*." *Id.* (emphasis added). In any event, the FDA has noted that repackaging approved drugs for resale is "beyond the practice of pharmacy and [is] thus subject to the requirements of premarket approval," with the only exception being repacking of solid oral dosage forms of products already approved under section 505 of the FDCA. *Id.*

83. In addition, under 21 C.F.R. § 211.87, "[c]omponents, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with 211.84 as necessary, *e.g.*, after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure."

84. The United States Pharmacopeial Convention is a scientific non-profit organization that publishes the United States Pharmacopeia ("USP"), which establishes professional standards for the identity, strength, quality, and purity of drugs. USP 797 sets forth professional standards for compounding drugs identified as sterile including, *inter alia*, standards for the cleaning and disinfecting of compounding areas; clean room surface and air filter requirements; action levels for microbial contamination; skills, education, instruction, and training for personnel; and gloved fingertip sampling. USP 797's standards are intended to prevent harm to patients that could result from non-sterility, which is especially dangerous to patients when the drugs would be administered via injectable medications.

c. *Labeling of Approved Drugs*

85. The FDCA requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. *See* 21 U.S.C. § 360.

86. Drug products are identified and reported using a unique, ten-digit, three-segment number, called the National Drug Code ("NDC"), which serves as a universal product identifier for human drugs.[5] The NDC identifies the labeler, product and trade package size.

87. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. A labeler code relevant to this action is 58063.

88. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm. Different formulations or different strengths of the same formulation should be assigned different product codes. This means that even if the same formulations of a drug product ultimately deliver different strengths of the active ingredient to the recipient, they should be assigned different product codes. Also, drug products that share the same formulation but have different product characteristics that clearly distinguish one drug product version from another cannot share the same product code under the same labeler code. A sample product code relevant to this action is 0797.

89. The third segment, the package code, identifies package sizes and types. Different package codes only differentiate between different quantitative and qualitative attributes of the product packaging. Both the product and package codes are assigned by the manufacturer/repackager/distributor. A sample package code relevant to this action is 25.

[5] The ten-digit, three-segment NDC will be in one of the following configurations: xxxx-xxxx-xx, xxxxx-xxx-xx, or xxxxx-xxxx-x. Letters are not used on valid NDCs.

90. The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory.

91. The term "label" is defined as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" is broader and includes all labels and other written, printed, or graphic matter on drugs, or any of its containers or wrappers, or on any written, printed, or graphic matter accompanying drugs. 21 U.S.C. § 321(m).

92. Drugs are considered misbranded if their labeling is false or misleading in any particular way. 21 U.S.C. § 352(a). Drugs are also considered misbranded if they are dangerous to a patient's health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 352(j).

93. It is illegal for anyone to introduce, deliver for introduction, or cause the introduction or delivery for introduction of misbranded drugs into interstate commerce. 21 U.S.C. § 331(a).

94. USP 797 further provides that all sterile drug products have to bear a "beyond use" or "use by" date, which was a date or time after which a compounded sterile preparation should not be stored or transported. Repackaged drugs similarly require a "beyond use" date, distinguishable from the scientifically-determined expiration date given by the original drug manufacturer.

d. *Recall*

95. When a drug is found to be defective or potentially harmful, the drug should be recalled from the marketplace to protect consumers. The FDA often assists pharmaceutical manufacturers or distributors with publicizing and carrying out a recall.

e. *Storage and Handling of Prescription Drugs*

96. Federal regulations further include certain minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees. 21 C.F.R. § 205.50.

97. These regulations provide that "[a]ll facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed" must:

> (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
> (2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
> (3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
> (4) Be maintained in a clean and orderly condition; and
> (5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

Id. § 205.50(a).

98. With respect to security, the regulations provide, in part, that "[e]ntry into areas where prescription drugs are held shall be limited to authorized personnel." *Id.* § 205.50(b)(1)(iii).

99. With respect to storage, the regulations provide that "[a]ll prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF)." *Id.* § 205.50(c). If there are no established storage requirements, "the drug may be held at 'controlled' room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely effected." *Id.* § 205.50(c)(1).

Moreover, appropriate equipment must be utilized, and precise recordkeeping requirements must be followed. *Id.* § 205.50(c)(2)–(3), (f).

100. "If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier," unless some investigation provides that the drug meets the appropriate standards. *Id.* § 205.50(e)(3).

2. Injectable Vials and the Required Overfill

101. Non-sterility, contamination, incorrect components, and errors in strength of correct components in sterile drug products are especially dangerous when the drugs are administered into vascular systems.

102. Thus, injectable drugs are often manufactured, packaged, and sold in single-use (dose) and multi-use (dose) sterile, glass vials.

103. Many drugs for cancer patients and for patients who are suffering from anemia, or nausea and vomiting, are manufactured in single-dose vials, meaning one vial per use per patient. Some drugs are manufactured in pre-filled single-dose syringes. And some are manufactured in multi-dose vials, meaning multiple injections for the same patient over a period of time, or multiple injections for multiple patients out of the same vial.

104. As with other FDA-approved drugs, each of these drugs has its own unique drug codes, or NDCs, which vary for each individual drug based on distribution method (vial, syringe, or auto-injector) and by the dose and quantity of the drug.

105. The amount of drug contained in each vial and the packaging of such drug for injection are pre-approved by the FDA and part of the package label.

106. Because there can be a slight loss of drug product from the withdrawal of the product from the original manufacturer container, the USP requires that injectable drug vials

contain a volume overage in "slight excess" of the labeled volume fill amount to permit withdrawal and administration of the label volume fill amounts. USP Reference Standards, XXXI Rockville, MD: (2008 Chapter 1151, page 619). This "slight excess" volume fill, or overage, is commonly referred to as the "overfill."

107. The sole purpose of overfill in a vial is to enable a medical provider to extract and administer the full labeled dose as prescribed by the physician and as approved by the FDA.

108. For as long as the Oncology Drugs have been on the market, the USP has recommended up to an additional .1 milliliter, or ten percent overfill, for a filled volume of up to one milliliter.

109. Many manufacturers, however, place additional overfill or excess volume in their vials to ensure that patients receive the proper amount from the vial and there is no shortage in the particular injection given to a particular patient.

110. FDA guidance directs manufacturers to document the amount and purpose of such overfill and to keep such reporting current. *See* FDA Guidance for Industry, "Q8 Pharmaceutical Development," Section 2.2.1, May 2006; *cf.* FDA Guidance for Industry, "M4: The CTD—Quality Questions and Answers/Location Issues, June 2004 (presenting as recommended for applications preparing the Common Technical Document for the Registration of Pharmaceuticals for Human Use that the use of and rationale for overfill should be indicated).

111. Overfill itself is not meant to be administered to a patient and is not paid for by anyone in the chain of distribution when purchasing the vial.

3. Reimbursement Framework for Injectable Vials

a. *Reimbursement for Incurred Expenses*

112. It has long been Medicare policy that services or supplies must represent an expense *actually incurred* by the healthcare provider to be reimbursed by Medicare.

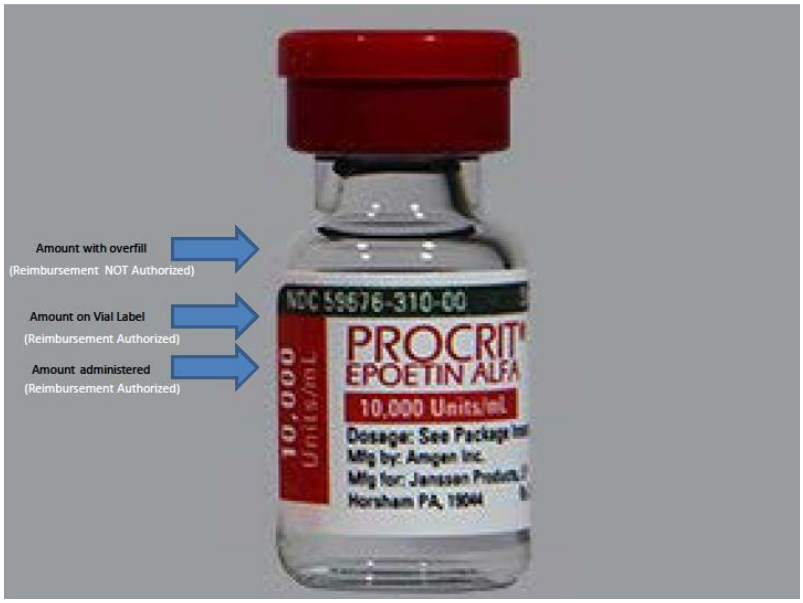
113. Specifically, the Medicare Benefit Policy Manual § 50.3 provides that "the cost of the drug or biological for which reimbursement is sought must represent an expense to the physician." The Medicare Benefit Policy Manual § 60.1A further provides that "[t]o be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing [for the] services or supplies." Medicare Benefit Policy Manual, Chapter 15 (Rev. 235, July 11, 2017) (language included since at least 2003).

114. Because healthcare providers incur no cost for overfill, overfill is not and never has been reimbursable by Medicare.

115. The Center for Medicare and Medicaid Services ("CMS") publishes a Program Integrity Manual reflecting "the principles, values, and priorities of the Medicare Integrity Program." Medicare Program Integrity Manual, Chapter 4, § 4.1. Under this manual, CMS identifies as the "most frequent kind of fraud . . . a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program." *Id.* § 4.2.1. CMS provides as one example of fraud "[b]illing non-covered or non-chargeable services as covered items." *Id.*

116. CMS set the reimbursement rates for these drugs to account for waste in the vial (the difference between the amount drawn and the label amount, as opposed to overfill, which is the difference between the label amount and the actual amount of drug product in the vial in excess of the label amount). As stated in the Medicare Claims Processing Manual: "When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of the drug/biological administered and the amount discarded, *up to the total amount of the drug/biological as indicated on the vial or package label*." Medicare Claims Processing Manual, Chapter 17, § 40

(Rev. 3538, June 9, 2016) (emphasis added). This language has been in the Medicare Claims Processing Manual since at least 2007, with inconsequential alterations. *See* Medicare Claims Processing Manual, Chapter 17, § 40 (revised July 2007) ("If after administering a dose/quantity of the drug or biological to a Medicare patient, a provider must discard the remainder of the single dose vial, the program provides payment for the amount of the drug/biological administered and the amount discarded, up to the total amount of the drug/biological as indicated on the vial or package label.").



117. Medicare reimburses these kinds of injectable drugs under its Part B program. CMS reimburses based on the ASP, which represents the drug manufacturer's total sales divided by the total number of units sold during the particular quarter. *See* 42 U.S.C. § 1395w-3a(c)(1)(A)-(B); *see also* U.S. Dep't of Health and Human Servs., *Average Sales Prices: Manufacturer Reporting and CMS Oversight* (Feb. 2010), *available at* https://oig.hhs.gov/oei/reports/oei-03-08-00480.pdf.

118. Manufacturers are required to "deduct the price concessions" from the numerator of this mathematical equation, which includes volume discounts, prompt pay discounts, cash

discounts, free goods that are contingent on any purchase requirement, charge backs, and rebates. *Id.* § 1395w-3a(c)(a); *see also* 42 C.F.R. § 414.804(a)(2)(i). Overfill is not explicitly mentioned in the statute as a type of price concession.

119. Acting in conjunction with the Office of Inspector General ("OIG"), the Secretary of HHS, which houses CMS, has authority to identify "other price concessions" beyond those already enumerated in the statute, but it has not done so with respect to overfill.

120. The exclusion of overfill as a price concession is, in fact, a conscious decision by CMS. In November 2010, the agency, consistent with its rule making authority, promulgated a clarifying rule with respect to "determining the payment amount for drugs and biologicals which include intentional overfill." Medicare Programs: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2011, 75 Fed. Reg. 73170, 73466 (Nov. 29, 2010). The rule states that, consistent with past policy, overfill is not included in the ASP calculation and that medical providers may not seek reimbursement for it.

121. In that regulation, Medicare clearly states that:

> It has been a long standing Medicare policy that 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. Such physicians' services and supplies include drugs and biologicals under Section 1861(s)(2)(A) of the Act. In accordance with this policy, provided they only bill for the amount of drug actually purchased and that the cost of the product must represent an expense to the physician.
>
> We further understand that when a provider purchases a vial or container of product, provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursed, and providers who submit such claims may be subject to scrutiny and follow up action by

> CMS, its contractors, and OIG.
>
> Because such overfill is currently not included in the calculation of payment limits under the methodology in Section 1847A of the Act and does not represent an incurred cost to the provider, we propose to update our regulations at 42 CFR Part 414 Subpart K to clearly state that the Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also propose our regulations at Subpart J to clearly state the payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label will not be made under Medicare. . . .

Id. at 73466–67.

122. CMS promulgated upgraded regulations, which state that "the manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA-approved label," 42 C.F.R. § 414.804(a)(6); that "CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label," *id.* § 414.904(a)(3)(i); that "additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit," *id.* § 14.904(a)(3)(ii); and that "no payment is made for amounts of product in excess of that reflected on the FDA-approved label," *id.* § 414.904(a)(3)(iii).

123. These regulations were specifically highlighted not to be new or substantive changes to previous Medicare policies, but rather clarifications of existing CMS policies. Specifically, CMS noted that "the intent of this proposal is merely to clarify that Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose." 75 Fed. Reg. at 73467; *see also id.* at 73468 ("[T]he intent of this proposal is to clarify that the ASP payment limit is currently based on the amount of drug indicated on the FDA label, and that no payment will be made for any intentional

overfill."), at 73468–69 ("[T]he intent of this proposal is to clarify that the ASP payment limit is based on the amount of drug clearly identified as the amount on the FDA label and packaging. We do not intend to change the ASP calculation methodology to include intentional overfill because of the operational difficulty in accurately identifying the amount of the overfill."), at 73469 ("[O]ur policy clarifies that we will not pay for intentional overfill.").

124. As noted by the regulations above and clarified through the more recent iteration of the CFR, because CMS deemed overfill "not reimbursable," 75 Fed. Reg. at 73466, it can have no independent value attached to it apart from the rest of the dosage in the vial. The only legitimate purpose of overfill is to ensure that providers and self-administering patients are able to draw up the full dosage amount the FDA recommends that manufacturers include for this purpose. *See* 56 Fed. Reg. at 35978.

125. In line with these rules, CMS never knowingly or intentionally reimbursed for overfill.

126. The industry was thus aware that Medicare prohibited providers from billing for overfill. *See* Buell, Roberta L., "Drug Wastage: A Payable Service?" *Managed Care Oncology* (managedcareoncology.com), Q1 2008 ("**Medicare provisions prohibit providers from billing overfill**." (emphasis in original)); Jim Musslewhite, "The waste conundrum," *Hematology & Oncology News & Issues*, Nov. 2009 ("CMS does not permit that overfill be billed due to the fact that it was not purchased.").

b. *Calculating the Reimbursement Rate*

127. CMS determines the reimbursement rate for injectable drugs based on each billing code and using a weighted average sales price calculated with the ASP data submitted by manufacturers.

128. Manufacturers submit ASP data at the eleven-digit NDC level by submitting the number of units of the eleven-digit NDC sold and the ASP for those units.

129. Beginning April 1, 2008, CMS began using a new weighting methodology to determine the payment limit. CMS sums the product of the manufacturer's ASP and the number of units of the eleven-digit NDC sold for each NDC assigned to the billing and payment code, and then divides this total by the sum of the product of the number of units of the eleven-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code. CMS weighs the ASP for an NDC by the number of billing units sold for that NDC. An example applying this calculation is included *infra*.

4. Reimbursement for Covered Drugs

130. To qualify as reimbursable, or "covered outpatient" drugs, drugs must be approved by the FDA. *See* 42 U.S.C. § 1396r–8(k)(2)(A)(i) (defining "covered outpatient drug" with respect to prescribed drugs, as a drug that may only be dispensed upon prescription and that is "approved for safety and effectiveness as a prescription drug under section 505 or 507 of the [FDCA]" or is a licensed biological product) (Medicaid); *see also id.* § 1395w–102(e)(1)(A) (defining "covered part D drug" as "a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title") (Medicare Part D); 42 C.F.R. § 423.100 (defining an applicable Part D drug as a drug that is "[a]pproved under a new drug application under section 505(b) of the [FDCA]" or is a licensed biological product).

131. Additionally, as previously explained, Congress expressly prohibits any person from introducing or receiving any "adulterated" or "misbranded" drugs in interstate commerce. 21 U.S.C. § 331(a), (c). A drug is "adulterated" if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not

operated or administered in conformity with current good manufacturing practice," or if "any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor." 21 U.S.C. § 351(a)(2)(B), (d). A drug is "misbranded" if "it is an imitation of another drug," or "it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" under the FDCA. 21 U.S.C. § 352(i)(2), (o). Violations of these restrictions are crimes, and adulterated or misbranded drugs can be seized. 21 U.S.C. §§ 333(a), 334.

5. How Distribution and Reimbursement For Oncology Drug Injections are Supposed to Work per the FDA and CMS Requirements.

132. For single-use vials, a physician would order a box of Oncology Drugs containing a number of single-use vials depending on how many patients requiring the Oncology Drugs the physician expected to have at different times. The physician would order the Oncology Drugs from distributors like Defendants, and Defendants would deliver the Oncology Drugs to the physician, who would then store/refrigerate the Oncology Drugs for use on individual patients.

133. Once the physician has withdrawn the prescribed amount (up to the labeled amount) from the vial, the residue is supposed to be discarded and may not be billed to any government program.

134. Using Procrit® as an example, one box of single-use vials of Procrit® contains four of the one ml vials; the concentration can vary between 2K, 3K, 10K, and 40K units, but the vial is always a one ml vial. Using the 40K unit vial, which would be labeled as such, each vial contains overfill of about ten percent above the labeled amount. So instead of having 40K units, the vial actually contains approximately 44K units. When the injection is drawn, 4K units are left over as residue. The residue is supposed to be discarded and may not be billed to any government program. The physician can bill only for 40K units, and nothing more.

135. For multi-use vials, a physician would order a box of Oncology Drugs containing a number of multi-use vials which, in the case of Procrit®, for example, come in four or six multi-use vials to the box.[6]

136. Again, using Procrit® as an example, which is manufactured in both single- and multi-use vials, the multi-use vials come in two different sizes and concentrations: two ml that has 20K units total (or 10K units per ml) or one ml that has 20K units total (or 20K units per ml). Using the two ml multi-use vial as an example, the vial has a label indicating content of 20K units. However, because of the standard ten percent overfill previously described, in reality the vial may contain approximately 22K units. When the injections are drawn, approximately 2K units are left over as residue. The residue is supposed to be discarded and may not be billed to any government program. The physician can bill for 20K units and nothing more.

II. SPECIFIC ALLEGATIONS OF DEFENDANTS' WRONGDOING

A. Manufacturing, Repackaging, and Distribution of Injectable Oncology Drugs

137. Defendants have engaged in a deliberate scheme through their Pre-Filled Syringe Program to repackage, re-manufacture, misbrand, and adulterate the injectable Oncology Drugs, or cause the same, and manipulate the ASP to increase their profits and increase reimbursement from the federal, state, and city reimbursement programs.

138. Defendants developed an intentional scheme, through their Pre-Filled Syringe Program, under which the FDA-approved manufacturing, processing, labeling, packing, and holding requirements as well as the CGMPs and USP guidelines were intentionally disregarded, evaded, or altered.

[6] Aloxi® is only sold by the manufacturer in single-use sterile vials.

139. At least in their facility in Frisco, Texas (later moved to Memphis, Tennessee), as previously described, Defendants pooled Oncology Drugs and their overfill from the FDA-approved packages in non-aseptic facilities, with insufficiently trained and skilled workers in non-aseptic clothing/gear, in a fashion that created adulterated and unapproved products placed into plastic pre-filled syringes, which in turn were then re-labeled (in some instances with fake product codes and expiration dates), then packaged and shipped in violation of FDA and drug-specific requirements.

1. Defendants' Process for Manufacturing, Labeling, Packing, and Shipping the Pre-Filled Syringes

140. The Oncology Drugs at issue are manufactured by "original manufacturers" that have been submitted to and approved through the regulatory process set forth by law and regulation to produce and sell drugs in the United States. Specifically, Aloxi® was manufactured by Eisai Inc.; Aranesp® and Neupogen® were manufactured by Amgen Inc.; Procrit® was manufactured by Ortho Biotech, Inc.; Kytril® was manufactured by Roche Pharmaceuticals; and Taxotere® was manufactured by Sanofi Aventis.

141. The Oncology Drugs would have been manufactured, labeled, and packaged for distribution and sale by the original manufacturers in accordance with approved FDA standards and would have had individual expiration dates.

142. The CGMPs require that each drug product bear an expiration date derived from tests conducted on samples stored in the immediate container closure system in which the drug is marketed. *See* 21 C.F.R. §§ 211.137, 211.166.

143. The single- and multi-use vials of the Oncology Drugs supplied by the original manufacturers to Defendants have a container closure system that was approved by the FDA as

part of the application process. The original container closure systems meet and are approved as meeting the stability regulations promulgated by the FDA at 21 C.F.R. §§ 166 and 211.137.

144. The single- and multi-use vial containers, in conformity with FDA requirements and having received FDA approval, were shipped from original manufacturers in sealed containers that were marked by lot and contained the number of units per volume, expiration date, and instructions on storage of the product until the product is used for patients, as well as the use of the product after use for patients.

145. At least in their facility in Frisco, Texas (later moved to Memphis, Tennessee), as previously described, Defendants acquired the Oncology Drugs in FDA-approved packaging from the original manufacturers, then uncapped, punctured, and removed the Oncology Drugs from the sterile, preservative-free, glass vials that had been filled and packaged by the original manufacturer with FDA approval and in accordance with the FDCA, CGMPs, and USP guidelines.

146. Additionally, apart from those physicians purchasing the Oncology Drugs in pre-filled syringes from US Oncology's distribution network, US Oncology's affiliated physician offices, vis-à-vis their staff, harvested overfill when administering the Oncology Drugs to their patients, specifically by extracting a particular patient dose, and then reentering the vial to harvest the remaining overfill, after which point they would pool the overfill with other drug product to fill another dose, all in violation of the Oncology Drugs' package instructions. The physician offices would not properly record that overfill, and would subsequently bill government reimbursement programs for that overfill.

147. Defendants' facilities and personnel, whether licensed or not, did not comply with the CGMPs' standards for: personnel engaged in quality control; the design, construction, and maintenance of buildings and facilities; the construction, cleaning, and maintenance of

equipment; the storage, inspection, and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage, and distribution; laboratory controls including testing of drug product batches for conformity with final specifications; maintenance of records and reports, and conduct of investigations; and procedures for handling of returned and salvaged product. As a result, Defendants' facilities concealed issues that would have led the Government to deny, or withdraw, registration.[7]

148. Defendants' facilities and personnel, whether licensed or not, did not comply with the USP's standards, including but not limited to standards for the cleaning and disinfecting of areas; clean room surface and air filter requirements; action levels for microbial contamination; skills, education, instruction, and training for personnel; and gloved fingertip sampling.

149. On information and belief, the facilities that Defendants used for their Pre-Filled Syringe Program:

> (1) were not of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
> (2) did not have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
> (3) did not have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
> (4) were not maintained in a clean and orderly condition; and
> (5) were not free from infestation by insects, rodents, birds, or vermin of any kind.

[7] Although over the relevant time period, McKesson listed one or two registered repackaging facilities—which are currently registered in Concord, North Carolina and Memphis, Tennessee—Defendants did not reveal their Pre-Filled Syringe Program to the governmental authorities, but rather touted more standard "bulk-to-bottle" repackaging, which likely left authorities with the impression that they were dealing with non-sterile products such as solid oral dosage forms.

150. On information and belief, entry into areas where Defendants held and repackaged the prescription drugs were not limited to authorized personnel.

151. On information and belief, Defendants did not store the Oncology Drugs at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the USP, or otherwise in such a way as to ensure that the drugs' identity, strength, quality, and purity were not adversely effected.

152. On information and belief, Defendants did not use appropriate equipment or maintain precise records with regard to the program.

153. On information and belief, Defendants did not perform appropriate tests to ensure the Oncology Drugs' safety, identity, strength, quality, or purity, and upon discovering issues, did not destroy or return the drugs to the manufacturer, or otherwise recall their syringes.

154. In violation of industry standards, established medical science, and the Oncology Drugs' labeling, Defendants punctured original, sterile glass vials more than once, transferred the Oncology Drugs into plastic syringes, and even pooled Oncology Drugs, including overfill, from multiple sources into a single pre-filled syringe.

a. *Re-entering Vials and Disregarding Package Inserts*

155. Many of the vials used by Defendants for these products were single-use vials, meaning that sterility could not be guaranteed if the vial was entered more than once.

156. Single-use vials are designed so that any excess from the first injection is discarded. This is because the Oncology Drug liquid is packed in a sterile container without preservatives, and any puncture, other than the first puncture, exposes the drug to risk of contamination.

157. By way of example, as far back as at least 1993, the package insert for Procrit® stated: "Use only one dose per vial; do not re-enter the vial. Discard unused portions. Contains no Preservative." Since at least July 26, 1999, the package insert for Procrit® single dose vials has said: "1 ml vial contains no preservative. Use one dose per vial; do not re-enter the vial. Discard unused portions."

158. Furthermore, in or around March 2000, Amgen circulated a letter to healthcare providers and dialysis clinicians because of twenty-one reported cases of bacteremia or pyrogenic reactions in patients receiving EPOGEN® at a U.S. dialysis clinic. *See* Ex. 1 (Amgen Letter). The letter reminded providers that "multiple entries should not be made into single dose vials, and residual medication from two or more vials should not be pooled into a single vial." *Id.* The letter further reminded providers that "[a]s supplied, EPOGEN® in single dose vials is a sterile solution" and "**DO NOT** contain a preservative," and that "[o]nce a syringe has entered a single dose vial, the sterility of the product can no longer be guaranteed." *Id.*

159. Since at least October 26, 2005, the Procrit® label and packaging were changed to now also state: "If you have been prescribed EPOGEN® vials for single use, your vial will have a capital "S" with a number next to it identifying the concentration of EPOGEN® in the vial, printed in a colored dot on the front left side of the label (for example, "S2" identifies a single use vial with 2000 Units/mL). Single use means the vial cannot be used more than once, and any unused portion of the vial should be discarded as directed by your doctor or dialysis center."[8]

160. A November 8, 2007 package insert states: "Unless you have been prescribed Multidose PROCRIT® (1 mL or 2 mL vials with a big "M" on the label, each containing a total of 20,000 Units of PROCRIT®), vials of PROCRIT® are for single use. Single use means the

[8] The FDA originally approved Epogen®/Procrit® (Epoetin alfa) on June 1, 1989.

vial cannot be used more than once, and any unused portion of the vial should be discarded as directed by your doctor."

161. And, a June 24, 2011 insert includes the following warnings: "Discard unused portions of Epogen in preservative-free vials. Do not re-enter preservative-free vials . . . Instruct patients who self-administer Epogen of the: Importance of following the Instructions for Use. Dangers of reusing needles, syringes, or unused portions of single-dose vials. . . . . Do not use a single-dose vial of Epogen more than one time. . . . Single-dose vials of PROCRIT should be used only one time. Throw the vial away after use even if there is medicine left in the vial. . . . Do not reuse the single-dose vials, syringes, or needles."

162. Similar warnings are contained on the package inserts for: Neopogen® single-dose vials and pre-filled syringes (since at least April 2, 1998), and Aranesp® single-dose vials and pre-filled syringes (since at least July 19, 2002).

163. In addition, since at least December 16, 2004, the package insert for Aranesp® has said: "Do not pool unused portions from the vials or prefilled syringes."

164. Relatedly, in 2001, the Centers for Disease Control and Prevention ("CDC") issued its Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. In that recommendation, the CDC warned that "Intravenous medication vials labeled for single use . . . should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial." Centers for Disease Control and Prevention, *Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients*, Apr. 27, 2001, Vol. 50, No. RR-5, at 19, *available at* https://www.cdc.gov/mmwr/PDF/rr/rr5005.pdf (last visited Feb. 1, 2018).

165. However, here the Defendants' personnel, in non-aseptic rooms, wearing non-aseptic garments, de-capped (opened) the vials and pooled the Oncology Drugs into larger syringes, with staff often entering a single vial two or three times to capture each drop of excess. This destroyed the documented sterility of the original glass vials, exposed the drugs to air and possible contaminants in an unsterile environment, and created an enormous risk of contamination.

166. After drawing up as much product as possible from each vial, the contents of the larger syringe—now including drugs from myriad vials—would be used to make a series of pre-filled syringes.

b. *Elimination of the Oncology Drugs' Pedigree*

167. A particular drug product must maintain a pedigree through its production from the factory to the patient. This is accomplished by issuing a lot number, which allows healthcare providers to trace contamination in any product. By pooling drug product from multiple vials and multiple lots into the pre-filled syringes, Defendants destroyed the pedigree of the product sold to healthcare providers, who could no longer determine the source of any infections as required by the FDCA, 21 U.S.C. § 503C(1)(A), and as discussed in FDA's CPG § 160.900.

168. When a healthcare provider ordered a pre-filled syringe manufactured by Defendants under the Pre-filled Syringe Program, he/she had no ability to determine the sterility, pedigree, or source of the syringe, as it may have been made from one vial or multiple vials harvested for their overfill.

169. In fact, Defendants concealed the nature of these drugs from providers on both the invoice and the pedigree. The invoice for a single-dose vial and a pre-filled syringe both stated

that the '"specific unit" was obtained "directly" from the manufacturer. *See* Ex. 2 (Invoices and Packing Slips).[9]

170. Specifically, for example, a Florida pedigree statement attested that: "For items on this invoice purchased directly from the manufacturer, OTN confirms that it has purchased and has received the specific unit of the prescription drug directly from the manufacturer, and has distributed the drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing." *See* Ex. 2 (Invoices and Packing Slips).

171. This presented an infection risk to patients who were already at a higher risk for infections given their immune-compromised state. As previously explained, should the source of an infection be from a pre-filled syringe manufactured or caused to be manufactured by Defendants, there would be no way to tell from which vial the adulterated material actually came from or whether the contamination occurred at Defendants' facilities.

c. *Preparing for Distribution*

172. Furthermore, in manufacturing their pre-filled syringes or causing the pre-filled syringes to be manufactured, Defendants used plastic syringes, unlike the glass vials that the FDA approved for the Oncology Drugs' original manufacture, to store and ship the Oncology Drugs. The plastic syringes were not designed for extended storage, but rather to administer injectable drugs. Instructions for many syringes stated that products placed therein should be administered "as soon as possible" after removal from the original vials. This created a particular problem with drugs, like Procrit®, Neupogen®, Aloxi®, and Aranesp®, which are largely preservative-free.

[9] Defendants routinely use abbreviations on their documents to identify what type of drug is purchased. "SDV" stands for Single-Dose Vial. "PF," "SYR," and "FOR PF" stand for Pre-Filled Syringe. "MDV" stands for Multi-Dose Vial. In the invoices, Defendants routinely listed a product as both SDV and PF.

173. Once mass production of their pre-filled syringes was complete, Defendants then grouped the pre-filled syringes into plastic bins, placed those plastic bins into plastic bags, and either (i) did not put expiration dates on the pre-filled syringes, or (ii) stamped new, fabricated expiration dates on the pre-filled syringes that did not correspond to the expiration dates on the vials or the relevant beyond-use dates, or otherwise comply with USP 797, notwithstanding the fact that the drugs were manufactured without preservatives and then repackaged under non-sterile conditions.

174. Defendants' behavior rendered the Oncology Drugs widely unsafe for administration. For example, Relator has confirmed that Aloxi®, when drawn into a syringe, is safe and effective for only forty-eight hours at room temperature, or fourteen days in the refrigerator, with the latter being the case only if aseptic procedure has been followed.

175. Defendants further manufactured their own fictitious NDC codes and/or placed the vials' NDC on the pre-filled syringes, as described in greater detail *infra*.

d. *Defendants' Awareness of Unsafe Practices*

176. Disturbingly, Defendants, along with the rest of the pharmaceutical industry, were aware of the danger inherent in these unsafe practices. Indeed, as described in greater detail above, the package inserts for the Oncology Drugs specifically advised Defendants not to engage in the very practices they were engaging in by re-entering preservative-free vials and pooling the contents of drugs. Moreover, representatives of the manufacturers of the Oncology Drugs specifically complained to Defendants about these practices.

177. Additionally, the CDC has long been focused on infection control, particularly for high risk patients such as oncology patients. Centers for Disease Control and Prevention, *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, available at* https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-

guidelines.pdf (last visited Jan. 19, 2018). Specifically, the CDC has identified a need to focus on safe injection practices following certain "primary breaches in infection control practice that contributed to" four large outbreaks, namely, (i) reinsertion of used needles into multi-dose vials or solution containers; and (ii) use of a single needle/syringe to administer intravenous medication to multiple patients. *Id.* at 68. The CDC noted that healthcare providers should not "administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use." *Id.* at 83.

178. The CDC itself emphasized that its safe injection practices have been in place since at least 2007. Indeed, in a statement titled "Misperceptions vs. Facts," the CDC identified as its "misinterpretation/misperception" that "Guidance regarding safe handling of single-dose/single-use vials is new and has only been in place since 2010," and the corresponding "fact" as being that "CDC injection safety guidelines are not new" and "have been part of Standard Precautions since 2007." Centers for Disease Control and Prevention, *Protect Patients Against Preventable Harm from Improper Use of Single-Dose/Single-Use Vials*, May 2, 2012, *available at* https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html (last visited Jan. 29, 2018).

179. On June 15, 2012, CMS issued a memorandum titled "Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections," in which it referenced "nationally recognized standards for infection control measures," which includes "the expectation that medications labeled as [single-dose vials] must not be used for multiple patients, due to the risk of spreading infectious diseases." Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality/Survey & Certification Group, *Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections*, June 15, 2012, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-

Certification/SurveyCertificationGenInfo/downloads/Survey-and-Cert-Letter-12-35.pdf (last visited Jan. 30, 2018). CMS noted that it had "received recent requests to relax its policies," but would not change its policy on the matter, explaining that while it "shares the concerns of providers and suppliers about patient access to critical medications," it is "equally concerned about health-care associated infections caused by unsafe medication preparation and injection practices." *Id.* The memorandum *clarified* its guidance regarding the various requirements, including reference to the FDCA's provisions related to adulteration or misbranded medications, as well as the USP standards with which companies must comply to avoid adulterating drugs.

e. *Inadequate Compliance Programs, Testing, or Safety Protocols*

180. On information and belief, Defendants had weak compliance programs in place. On information and belief, they failed to: (i) conduct a thorough investigation; (ii) implement corrective action to terminate and remedy any improper conduct; or (iii) disclose the improper conduct to the appropriate agency or U.S. Attorney's Office.

181. On information and belief, Defendants did not have: (i) a lead compliance officer at the senior management level with supervision over the Pre-Filled Syringe Program; (ii) requirements that middle management periodically certify FCA compliance for their units; (iii) an anonymous whistleblower hotline or e-mail system; (iv) regular notifications sent to employees informing them how to report a potential FCA or other problem; (v) consistent follow-up on all internal reporting and whistleblowing tips; (vi) internal audits of business systems; (vii) recurring training regarding the FCA, anti-fraud and anti-kickback policies, and employees' obligation to report potential wrongdoing; (viii) widespread availability of an updated compliance guidebook tailored to the company's industry and policies; or (ix) consistent messaging from management and supervisors emphasizing the importance of compliance with the FCA or FDCA.

2. Defendants' Order Forms

182. To order pre-filled syringes from Defendants, healthcare providers were required to fill out a specific "Pre-filled Syringe Order Form." *See* Ex. 3 (Pre-filled Syringe Order Forms). Defendants would provide this order form to healthcare providers, who would then fax or email back to Defendants the order form indicating the quantity of pre-filled syringes to be ordered. Indeed, representatives of Defendants and McKesson Specialty Care Solutions affirmed that "[e]ach time an order for the pre-filled syringes [is] placed this form has to be faxed into the number on the bottom of the form." *See* Ex. 4 (Sept. 4, 2009 Email).

183. In fact, Defendants' order forms did not even allow healthcare providers to insert patient-specific information when ordering pre-filled syringes. *See* Ex. 3 (Pre-filled Syringe Order Forms). The order forms only provided spaces for healthcare providers to fill out the practice information and indicate the order quantity for each prescribed drug.

184. Defendants' process for receiving orders for pre-filled syringes was markedly different from their ordering process for vials or other chemotherapy drugs. When healthcare providers would order vials, they would instead do so electronically vis-à-vis Defendants' e-commerce portal, or place the order by telephone.

185. After Relator would place an order, it would pay by direct debit from its checking account the following day, or within forty-eight hours.

186. As evident by the order forms, Defendants were not preparing these syringes on a patient- specific basis. Rather, Defendants regularly dispensed pre-filled syringes without a valid prescription for a specific patient.

187. In addition, Relator has specific knowledge, from ordering pre-filled syringes in the past, that orders can be placed up until 6:00 p.m. for delivery the next day. Taking into

account the time necessary to deliver the product to FedEx for overnight delivery, there would be no time to manufacture the syringes and get them shipped if they were truly patient-specific.

188. Defendants were manufacturing these syringes throughout the day and merely fulfilling bulk orders when received by providers.

3. Other Safety Issues Arising from the "Pre-Filled Syringe Program"

189. As explained in greater detail *supra*, Defendants maintained non-aseptic conditions in their facilities and technicians did not wear sterile gowns, otherwise take the requisite precautions, or follow appropriate procedures.

190. Additionally, many of the FDA-approved labels on the Oncology Drugs used to create pre-filled syringes had instructions regarding storage and handling. For example, many drugs are so-called "cold chain" drugs, meaning that the drug is temperature sensitive and must maintain a specific managed temperature as it moves through the supply chain. Procrit® was one such drug, and its label required that the drug be stored at 36° to 46° Fahrenheit and stated: "Do not freeze or shake." The label for Aranesp® contained the same instructions, and also stated to "[p]rotect from light." Kytril® was to be stored at 77° Fahrenheit, with "excursions" permitted to 59° to 86° Fahrenheit, and its label similarly told reviewers that they should "not freeze" and should "[p]rotect from light." The label for Neupogen® instructed that "NEUPOGEN® should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer. Avoid shaking NEUPOGEN®. . . . NEUPOGEN® can be left out at room temperature for up to 24 hours. Do not leave NEUPOGEN® in direct sunlight." And, the label for Taxotere® stated to "Store between 2 and 25°C (36 and 77°F). Retain in the original package to protect from bright light."

191. However, notwithstanding these precise instructions, Defendants manufactured and repackaged the Oncology Drugs in room temperature with bright room lighting.

4. Defendants Provided Misbranded, Adulterated, and Unapproved Drugs Into the Stream of Commerce

192. Defendants took the single- and multi-use vials, as prepared and sold by the manufacturer, and adulterated them to create new pre-filled syringes, which they then marketed and sold to physicians and other health care providers as pre-filled syringes. These pre-filled syringes were not created in compliance with FDA requirements, and Defendants labeled and packaged them with new expiration dates and altered NDC codes not approved by the FDA or otherwise in accordance with the FDA's drug-specific labeling and requirements.

193. Pursuant to FDA regulations, and as further explained above, the Agency must be notified in advance when there is a major change in the drug product including a change in primary packaging components for drug products or for sterile drug products a change to a pre-filled dosage from another container system. 21 C.F.R. §§ 324.70, 601.12; *see also* Guidance for Industry, *Changes to an Approved NDA or ANDA*, April 2004 (the "Guidance"); Guidance for Industry, *Changes to an Approved Application, Biological Products*, July 1997.

194. The Guidance explains:

> **Major Changes (Prior Approval Supplement)**
> The following are examples of changes considered to have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.
>
> A change in the primary packaging components for any drug product when the primary packaging components control the dose delivered to the patient (e.g., the valve or actuator of a metered-dose inhaler).
>
> ***
>
> 4. For sterile drug products, any change that may affect drug product sterility assurance, such as:
>
> -A change from a glass ampule to a glass vial with an elastomeric closure.
>
> -A change to a flexible container system (bag) from another container system.
>
> -A change to a prefilled syringe dosage form from another container system.

-A change from a single unit dose container to a multiple dose container system.

-Changes that add or delete silicone treatments to container closure systems (such as elastomeric closures or syringe barrels).

-Changes in the size and/or shape of a container for a sterile drug product

195. Defendants did not notify the FDA in advance or otherwise obtain approval for the major changes they effected to the Oncology Drugs.

196. As explained in greater detail above, the creation of the pre-filled syringes by Defendants consists of preparing and packaging a product that is different from that which was created, prepared, packaged and supplied by the original manufacturer.

197. The pre-filled syringes are not prepared under FDA-approved conditions, are not in an FDA-approved container, lack FDA-approved stability via a container closure system, and lack an FDA-approved expiration date. Defendants' process of manufacturing the pre-filled syringes is also inconsistent with the Oncology Drugs' labeling, as described above and further explained below, such that Defendants are distributing unapproved new drugs and biologics in violation of sections 505 and 507 of the FDCA, and misbranded drugs in violation of section 502(f)(1) of the FDCA.

198. Defendants' pre-filled syringes were packaged with false and misleading labeling and thus misbranded pursuant to 21 U.S.C. § 352(a). Defendants' pre-filled syringes were also misbranded because they were dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 352(j).

199. Defendants introduced, delivered for introduction, or caused the introduction or delivery for introduction of misbranded drugs into interstate commerce. 21 U.S.C. § 331(a).

200. The FDA approved Aloxi® for two dosage forms: an oral capsule, which has since been discontinued, and single-use vials: "ALOXI® is supplied as a single-use sterile, clear, colorless solution in glass vials that provides 0.25 mg (free base) per 5 mL."

201. Defendant McKesson's catalogue lists two types of Aloxi® for sale: (i) a .25 mg (presumably single dose vial); and (ii) a .25 mg PF Syringe (PF for pre-filled syringe). *See* Ex. 5 (McKesson Manufacturer Contract Price Change Alert); *see also* Ex. 2 (Invoices and Packing Slips).

202. The McKesson Manufacturer Contract Price Changes document from the McKesson PFS Catalogue for Aloxi® and Procrit®, and also referencing OTN, shows an NDC number for Aloxi® in the PF Syringe as 58063-0797-IJ. This document was emailed to Relator in January 2008. The IJ designation was not an approved NDC number, further evidencing the fact that the pre-filled syringes were created by the Defendants outside of the FDA-approved manufacturing process.

203. The Eisai Reimbursement Code Information Sheet lists two NDC codes for Aloxi®, neither of which is the NDC code listed by McKesson with an IJ ending. *See* Ex. 6 (Eisai Reimbursement Codes Information Sheet). This same document does not indicate that Eisai sells a pre-filled syringe.

204. The same is true for Procrit®. McKesson and OTN advertised selling Procrit® in a 40,000 U/ML PF Syringe (pre-filled). *See* Ex. 5 (McKesson Manufacturer Contract Price Change Alert). Yet, the FDA has only approved Procrit® in single- or multi-use vials.

205. There is no FDA approval for a pre-filled syringe of Procrit®, Aloxi®, Kytril®, and Taxotere®.

206. Defendants sent invoices to customers, including Relator, some that were captioned specifically for pre-filled syringes and others that listed Aloxi® sales of .05 mg/ml syringes, a dose and packaging not approved by the FDA.

207. Additionally, the Procrit® being sold by Defendants as listed on the McKesson PFS Catalogue includes an NDC code with an "IJ" ending, not the NDC code on record with the FDA.

208. Defendants, through their Pre-Filled Syringe Program and the above described actions, have engaged in the manufacturing and distributing of drugs for human use and placed their pre-filled syringes into commerce and for human use without FDA approval.

209. Defendants have not complied with the provisions of the FDCA applicable to manufacturers and are manufacturing unapproved and adulterated drugs; thus, their pre-filled syringes were not legally being manufactured or sold in commerce and were not reimbursable by any governmental or private insurance company.

210. Drugs are deemed to be adulterated if they are not manufactured in compliance with the CGMPs or if they are contaminated. 21 U.S.C. § 351(a)(2)(A)(B).

211. As explained above, Defendants' pre-filled syringes are not manufactured in compliance with CGMPs or USP guidelines and pose a significant safety risk of infection.

212. By pooling the Oncology Drug liquid from the single- and multi-use vials, including the overfill, and using it collectively to create pre-filled syringes, Defendants are creating and selling adulterated, unapproved, and compounded drugs, which may not be sold in commerce and which are not reimbursable by any governmental or private insurance company. This would apply to the all products sold by Defendants under the Pre-Filled Syringe Program, whether from overfill or not.

213. As previously explained, for purposes of Medicare, Medicaid, and other government programs, a "covered outpatient drug" is one that is approved for safety and effectiveness by the FDA. The Oncology Drugs were largely not approved for manufacture in pre-filled syringes, and to the extent they were so approved, pre-filled syringes from pooled vials were not approved. Even had Defendants applied for and received approval, approval likely would have been withdrawn, as under 21 U.S.C. § 355(e)(5), approval may be withdrawn if "there is an imminent hazard to the public health" and if "the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drag are inadequate to assure and preserve its identity, strength, quality, and purity." By pooling the overfill from the Oncology Drugs, Defendants acted as manufacturers and distributed drug product that did not possess the requisite assurance of identity, strength, quality, and approval required by the FDA, and then concealed its operations from the governments. Therefore, among other reasons listed above, the Oncology Drugs were not "covered" drugs, and claims submitted for those drugs were false.

5. Defendants Submitted, or Caused, Claims for Reimbursement

214. Apart from the claims US Oncology itself submitted to the governments for reimbursement on behalf of its physicians and providers, Defendants caused thousands of claims to be submitted by healthcare providers to the governments.

215. For example, during the 2007-2010 time period that Relator ordered pre-filled syringes of Procrit® and Aloxi® from Defendants, Relator submitted hundreds of bills for reimbursement to Medicare or Medicaid. *See* Ex. 7. And, approximately sixty percent of Relator's roughly $3 million annual spend on pre-filled syringes distributed by Defendants was submitted to governmental reimbursement programs.

216. Relator believes that the damages to the governments amount to hundreds of millions of dollars, based at least on (i) the size of McKesson's operations; and (ii) the significant and systematic regulatory violations, and the adulterated, unapproved, and misbranded drugs that were introduced into commerce and paid for by the governments as a result.

B. Unlawful Profiting from the Sale of the Pre-Filled Syringes and Improper Manipulation of the ASP

217. Defendants sold their newly-repackaged pre-filled syringes to healthcare providers through contractual agreements.

218. The agreements provided financial incentives or kickbacks, such as discounts, to the physicians to buy Defendants' Oncology Drugs via their Pre-Filled Syringe Program as opposed to purchasing the Oncology Drugs in the single-dose or multi-dose vials packaged by the original manufacturers and approved by the FDA for interstate commerce and human use. For example, in or around September 2007, a pre-filled syringe of Procrit® cost $327.42, whereas a vial of Procrit cost $346.99.

219. The discounts provided were made possible through the "free" overfill drugs, for which Defendants had not paid the manufacturers, creating kickbacks to healthcare providers in violation of the law while Defendants simultaneously told healthcare providers that its practices were legal.

220. For every pre-filled syringe ordered by a healthcare provider, McKesson would bill the practice at a price discounted from the regular vial price, and then prepare and ship a corresponding pre-filled syringe. During the relevant time period, millions of pre-filled syringes were sold and shipped to oncology practices. Defendants did not report the free injections created by the pooling used to create the pre-filled syringes.

221. Because of these discounts, approximately ninety-five percent of the relevant drugs ordered from Defendants by the Relator in the 2007-2010 time period were pre-filled syringes.

222. Relator alone spent approximately $3 million annually from 2007-2010 on pre-filled syringes distributed by Defendants, with approximately eighty percent of that spend on Procrit® pre-filled syringes, and twenty percent on Aloxi® pre-filled syringes.

223. Additionally, because of their practice of pooling overfill from multiple vials into pre-filled syringes and harvesting of overfill, Defendants created a larger quantity of syringes for sale than what existed in the packaging distributed by the original manufacturer. Therefore, Defendants billed healthcare providers, who in turn unknowingly billed the governments, for more drug product than was originally billed to them by the manufacturers. For example, if a drug had ten percent overfill, and Defendants received 1,000 vials, they would manufacture 1,100 pre-filled syringes, and thus charge customers for 1,100 pre-filled syringes at the discounted price. Given the large scale at which Defendants manufactured their drug products, their Pre-Filled Syringe Program thereby allowed them to gain immense profit at the ultimate financial expense of the governments.

224. On top of causing healthcare providers to improperly invoice the governments, US Oncology itself submitted false claims for reimbursement to the federal, state, and local government programs.

225. The harm caused by Defendants to the governments expands far beyond the sale of overfill. Indeed, Defendants' conduct artificially inflated the ASP for every drug sold in every package that is ultimately utilized in the Pre-Filled Syringe Program.

226. Defendants skewed the ASP process by introducing product into commerce specifically excluded from the calculation of ASP. As such, the injections manufactured by

Defendants were reimbursed at a rate set by CMS through the reported data from the original manufacturer, which yielded a reimbursement rate that was higher per dose than the actual ASP for that drug sold because these pre-filled injections created by Defendants containing free product were never calculated in setting the price, causing damage to the governments.

227. Taking, for example, the calculus used to determine the ASP after April 1, 2008, if the ASP for a specific NDC was $10, and a company sold 50,000 of that NDC, with the total amount of the drug being 2ml and the billing units in the NDCs being 0.4, then the volume weighted ASP for that code would have been the product of $10 and 50,000, divided by the product of 50,000 and 0.4, or $25. However, had the total amount of drug in the NDC accounted for the overfill, and had the overfill been another ten percent, or 0.2ml, giving a total of 2.2ml, or 0.44 billing units in the NDC, then the same calculation would lead to a volume-weighted ASP of $22.73.

228. Defendants are sharing this discount with healthcare providers by charging providers less for purportedly the same amount of drug product in a pre-filled syringe than they would for a glass vial. By way of illustration, if Defendants paid $100 per vial for 100 vials, or $10,000 total, and then created 110 pre-filled syringes from those 100 vials, they could charge healthcare providers $99 for each pre-filled syringe. Healthcare providers, seeking to purchase 100 vials, could then buy those 100 vials as pre-filled syringes for $9,900 instead of the $10,000 they would spend purchasing directly from the manufacturer. Although charging less per pre-filled syringe, Defendants would garner $10,890 for 110 pre-filled syringes.

229. This allowed Defendants to sell these adulterated injections downstream from the data reporting used by CMS to set reimbursement, and, therefore, CMS and government payment programs were paying for more injections than were originally represented to CMS as being in commerce.

230. Defendants intentionally initiated and promulgated the Pre-Filled Syringe Program to place into commerce adulterated and unapproved injections created in whole or in part from harvested overfill from vials of drugs, and to submit or cause to be submitted false claims to the federal, District of Columbia, state, and city reimbursement programs. As described in greater detail above, at all times, Defendants were aware, along with the rest of the pharmaceutical industry, that the practice of mass-producing pre-filled syringes and billing for the overfill contained therein was unlawful.

231. However, on information and belief, Defendants neither sought FDA approval for these drugs nor reported data as a manufacturer to CMS for ASP purposes.

232. Defendants thereby knowingly presented or caused to be presented false claims to the governments when, among other things, they: (i) unlawfully manufactured, promoted, and distributed drugs that were unapproved by the FDA; (ii) unlawfully manufactured, promoted, and distributed adulterated and misbranded drugs that were compromised, lacking purity, and generally below the standards they were represented or expected to possess by the governments; (iii) improperly harvested overfill, such that the governments were billed improperly for drug product that was not covered for reimbursement; (iv) improperly harvested overfill and made misrepresentations of fact that affected the ASP and reimbursement of the Oncology Drugs; and (v) provided financial inducements healthcare providers to purchase the pre-filled syringes.

233. Defendants knowingly engaged in the conduct described herein and thus violated the applicable statutes and regulations, including, but not limited to, the Anti-Kickback Act and various False Claims Acts. By engaging in this conduct, Defendants induced excessive payments from federal, District of Columbia, state, and local governments, created the potential for patient harm, and generated excess income.

234. Had the federal, District of Columbia, state, or local governments been aware of the conduct alleged in this Second Amended Complaint, they would not have paid the claims that were submitted as a result of Defendants' misconduct.

235. On information and belief, at no time since Defendants were aware that they had violated the law and had an obligation to reimburse the governments have they done so.

CLAIMS FOR RELIEF

COUNT 1

Federal False Claims Act: Presentation of False Claims
(31 U.S.C. § 3729(a)(1))

236. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint as if fully set forth herein.

237. By virtue of the acts alleged herein, Defendants, through the acts of their officers, agents, employees, and sales representatives and for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid, and other Government health programs to officers, employees, or agents of the United States Government, in violation of 31 U.S.C. § 3729(a)(1).

238. As a result, federal monies were lost through payments made in connection with the claims and other costs and losses were sustained by the Government, and Defendants are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim made and caused to be made by Defendants, and arising from their conduct as described herein.

COUNT 2

Federal False Claims Act: False Statements
(31 U.S.C. § 3729(a)(2))

239. Relator repeats and incorporates the preceding paragraphs of this Second Amended Complaint as is fully set forth herein.

240. In performing the acts described above, Defendants, through the acts of their officers, agents, employees, and sales representatives, knowingly made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the Government in violation of 31 U.S.C § 3729(a)(2).

241. The United States, unaware of the foregoing circumstances and conduct of Defendants, made full payments, and Defendants are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim paid or approved, arising from Defendants' conduct as described herein.

COUNT 3

Federal False Claims Act: Making or Using False Record
or Statement to Avoid an Obligation to Refund
(31 U.S.C. § 3729(a)(7))

242. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint as if fully set forth herein.

243. By virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States in violation of 31 U.S.C. § 3729(a)(7).

244. Despite knowing that Defendants owe money to the United States in connection with their unlawful conduct set forth herein, they have neither admitted nor paid the amounts owed.

245. Defendants are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim submitted.

COUNT 4

Federal False Claims Act: Conspiracy to Violate the False Claims Act
(31 U.S.C. § 3729(a)(3))

246. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 124 of this Second Amended Complaint as if fully set forth herein.

247. By virtue of the acts alleged herein including the joint marketing of Defendants' Pre-Filled Syringe Program with other wholesale distributors through the use of coordinated industry wide pushes for the use of pre-filled syringes and discounts created through the use of overfill, Defendants knowingly entered into a conspiracy to defraud the Government by getting a false or fraudulent claim allowed or paid, and agreed that the false records or statements would have a material effect on the Government's decision to pay the false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(3).

248. As a result, federal monies were lost through payments made, and Defendants are liable for treble damages plus the maximum civil penalty of $10,000 for each and every false and fraudulent claim.

COUNT 5

Payment Under Mistake of Fact

249. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

250. This is an action to recover monies paid by the federal, state, and local governments under a mistake of fact that was caused by Defendants through the activities described in the Second Amended Complaint.

251. The United States of America, District of Columbia, states, and cities made payments for pre-filled syringes under the erroneous belief that the records, statements, and proposed amount upon which reimbursement was based were true, correct and proper.

252. These erroneous beliefs were material to the payments made by the states, cities, District of Columbia, and Federal Government.

253. The United States of America, states, District of Columbia, and cities were not aware that the claims submitted to them for reimbursement were for pre-filled syringes, as opposed to the FDA-approved vials. Indeed, the claims submitted for reimbursement did not identify whether the drug for which the party was seeking reimbursement was provided in a pre-filled syringe or other container.

254. Because of these mistakes of fact, the United States of America, District of Columbia, states, and cities paid monies for the pre-filled syringes that were not properly reimbursable and to which the United States of America, District of Columbia, states, and cities are entitled.

255. By reason of these payments, the United States of America, District of Columbia, states, and cities have suffered damages in an amount to be determined.

COUNT 6

Unjust Enrichment

256. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

257. The Defendants colluded amongst themselves to convey benefits on Defendants to the detriment of Plaintiffs.

258. Defendants caused themselves to be enriched and conveyed benefits on themselves at the expense of the United States of America, District of Columbia, states, and

cities under circumstances where it would be inequitable for Defendants to retain the benefits conveyed.

259. The benefits conveyed to Defendants were conveyed independent from, and outside the scope of, any agreement between Plaintiffs and Defendants.

260. In equity and good conscience, it would be unfair for Defendants to retain any such benefits.

261. Each Defendant should be required to disgorge any such benefit in amounts to be determined at trial to Plaintiffs.

COUNT 7

California False Claims Act
(Cal. Gov't Code § 12651(a)(1))

262. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

263. This is a claim for penalties and treble damages for violation of the California False Claims Act.

264. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other California State-funded programs to officers or employees of the state within the meaning of Cal. Gov't Code § 12651(a)(1).

265. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other California State-funded programs within the meaning of Cal. Gov't Code § 12651(a)(2).

266. The California State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

267. As a result, California State monies were lost through payments made because of the claims, and other costs and losses were sustained by the California State Government.

268. Therefore, the California State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

269. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 8

Colorado Medicaid False Claims Act
(C.R.S.A. § 25.5-4-300.4 *et seq.*)

270. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

271. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

272. By virtue of the acts described above, Defendants, for the purpose of defrauding the Colorado State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Colorado State-funded programs within the meaning of C.R.S.A § 25.5-4-304.

273. The Colorado State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

274. As a result, Colorado State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Colorado State Government.

275. Therefore, the Colorado State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

276. Additionally, the Colorado State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' conduct as described herein as well as costs as permitted under the statute.

COUNT 9

Connecticut False Claims Act
(C.G.S.A. § 17b-301 *et seq.*)

277. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

278. This is a claim for penalties and treble damages under the Connecticut False Claims Act.

279. By virtue of the acts described above, Defendants, for the purpose of defrauding the Connecticut State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Connecticut State-funded programs within the meaning of C.G.S.A § 17b-301(a) and (b).

280. The Connecticut State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

281. As a result, Connecticut State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Connecticut State Government.

282. Therefore, the Connecticut State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

283. Additionally, the Connecticut State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' conduct as described herein as well as costs as permitted under the statute.

COUNT 10

Delaware False Claims and Reporting Act
(6 Del. C. § 1201 *et seq.*)

284. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

285. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

286. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly presented and/or caused to be presented, directly or indirectly, false or fraudulent claims for payment or approval under Medicaid and other Delaware State-funded programs to officers or employees of the state within the meaning of 6 Del. C. § 1201(a)(1).

287. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly made, used, and/or caused to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Delaware State-funded programs within the meaning of 6 Del. C. § 1201(a)(2).

288. The Delaware State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

289. As a result, Delaware State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Delaware State Government.

290. Therefore, the Delaware State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted under the statute.

291. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 11

District of Columbia Procurement Reform Amendment Act
(D.C. Code § 2-308 *et seq.*)

292. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

293. This is a claim for penalties and treble damages under the District of Columbia Procurement Reform Amendment Act.

294. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly presented and/or caused to be presented, false claims for payment or approval under Medicaid and other District of Columbia-funded programs to officers or employees of the District within the meaning of D.C. Code § 2-308.14(a)(1).

295. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other District of Columbia-funded programs within the meaning of D.C. Code § 2- 308.14(a)(2).

296. The District of Columbia Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

297. As a result, District of Columbia monies were lost through payments made because of the claims, and other costs and losses were sustained by the District of Columbia Government.

298. Therefore, the District of Columbia Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

299. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 12

Florida False Claims Act
(Fla. Stat. § 68.082 *et seq.*)

300. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

301. This is a claim for penalties and treble damages under the Florida False Claims Act.

302. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Florida State-funded programs to officers or employees of the state within the meaning of Fla. Stat. § 68.082(2)(a).

303. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Florida State-funded programs within the meaning of Fla. Stat. § 68.082(2)(b).

304. The Florida State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

305. As a result, Florida State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Florida State Government.

306. Therefore, the Florida State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

307. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 13

Georgia State False Medicaid Claims Act
(Ga. Code Ann. § 49-4-168 *et seq.*)

308. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

309. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

310. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly presented and/or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval within the meaning of Ga. Code Ann. § 49-4-168.1(a)(1).

311. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program within the meaning of Ga. Code Ann. § 49-4-168.1(a)(2).

312. The Georgia State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

313. As a result, Georgia State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Georgia State Government.

314. Therefore, the Georgia State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

315. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented or caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 14

Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21 *et seq.*)

316. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

317. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

318. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Hawaii State-funded programs to officers or employees of the state within the meaning of Haw. Rev. Stat. § 661-21(a)(1).

319. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly made, used, and/or caused to be made or used, false

records or statements to get false or fraudulent claims paid or approved under Medicaid and other Hawaii State-funded programs within the meaning of Haw. Rev. Stat. § 661-21)(a)(2).

320. The Hawaii State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

321. As a result, Hawaii State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Hawaii State Government.

322. Therefore, the Hawaii State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

323. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 15

Illinois Whistleblower Reward and Protection Act
(740 Ill. Comp. Stat. § 175/3(a))

324. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

325. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward and Protection Act.

326. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Illinois State-funded programs to officers or employees of the state within the meaning of 740 Ill. Comp. Stat. § 175/3(a)(1).

327. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Illinois State-funded programs within the meaning of 740 Ill. Comp. Stat. § 175/3(a)(2).

328. The Illinois State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

329. As a result, Illinois State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Illinois State Government.

330. Therefore, the Illinois State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

331. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 16

Indiana False Claims and Whistleblower Protection Act
(Ind. Code § 5-11-5.5-2 *et seq.*)

332. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

333. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

334. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally presented and/or caused or induced another to present false claims under Medicaid and other Indiana State-funded programs to the state for payment or approval within the meaning of Ind. Code § 5-11-5.5-2(b)(1) and (8).

335. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally made, used, and/or caused or induced another to make or use, false records or statements to obtain payment or approval of a false claim under Medicaid and other Indiana State-funded programs within the meaning of Ind. Code § 5-11-5.5-2(b)(2) and (8).

336. The Indiana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

337. As a result, Indiana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Indiana State Government.

338. Therefore, the Indiana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

339. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from Defendants' conduct as describe herein.

COUNT 17

Iowa False Claims Act
(I.C.A. § 685.2 *et seq.*)

340. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

341. This is a claim for penalties and treble damages under the Iowa False Claims Act.

342. By virtue of the acts described above, Defendants, for the purpose of defrauding the Iowa State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Iowa State-funded programs within the meaning of I.C.A. § 685.2et seq.

343. The Iowa State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

344. As a result, Iowa State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Iowa State Government.

345. Therefore, the Iowa State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

346. Additionally, the Iowa State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' conduct as described herein as well as costs as permitted under the statute.

COUNT 18

Louisiana Medical Assistance Programs Integrity Law
(La. Rev. Stat. § 46:438.3(A) and (B))

347. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

348. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

349. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Louisiana State-funded programs within the meaning of La. Rev. Stat. § 46:438.3(A).

350. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of La. Rev. Stat. § 46:483.3(B).

351. The Louisiana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

352. As a result, Louisiana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Louisiana State Government.

353. Therefore, the Louisiana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

354. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. § 46:438.6(B)(2).

COUNT 19

Maryland False Claims Act
(Md. Code Health General § 2-601 *et seq.*)

355. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

356. This is a claim for a fine and damages under the Maryland False Claims Act.

357. By virtue of the acts described above, Defendants, for the purpose of defrauding the Maryland State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of Md. Code Health General § 2-601-602).

358. The Maryland State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

359. As a result, Maryland State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Maryland State Government.

360. Therefore, the Maryland State Government has been damaged in an amount to be proved at trial.

361. Additionally, the Maryland State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. Md. Code Health General §2-602).

COUNT 20

Massachusetts False Claims Act
(Mass. Gen. L. Ch. 12, § 5B(2))

362. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

363. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

364. By virtue of the acts described above, Defendants, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth within the meaning of Mass. Gen. L. Ch. 12, § 5B(2).

365. The Massachusetts Commonwealth Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

366. As a result, Massachusetts Commonwealth monies were lost through payments made because of the claims, and other costs and losses were sustained by the Massachusetts Commonwealth Government.

367. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

368. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' conduct as described herein.

COUNT 21

Michigan Medicaid False Claims Act
(Mich. Comp. Laws § 400.601 *et seq.*)

369. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

370. This is a claim for damages and a civil penalty under the Michigan Medicaid False Claims Act.

371. By virtue of the acts described above, Defendants, for the purpose of defrauding the Michigan State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Michigan a claim under the Social Welfare Act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the State, knowing the claim to be false within the meaning of Mich. Comp. Law § 400.601 et seq.

372. The Michigan State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

373. As a result, Michigan State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Michigan State Government.

374. Therefore, the Michigan State Government has been damaged in an amount to be proved at trial.

375. Additionally, the Michigan State Government is entitled to a civil penalty equal to the full amount of the benefit received by Defendants plus triple the amount of damages suffered by the state as a result of the conduct by Defendants as described herein.

COUNT 22

Minnesota False Claims Act
(Minn. Stat. § 15C.01 *et seq.*)

376. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

377. This is a claim for penalties and treble damages under the Minnesota False Claims Act.

378. By virtue of the acts described above, Defendants, for the purpose of defrauding the Minnesota Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Minnesota Government within the meaning of Minn. Stat § 15C.01.

379. The Minnesota Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

380. As a result, Minnesota monies were lost through payments made because of the claims, and other costs and losses were sustained by the Minnesota Government.

381. Therefore, the Minnesota Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

382. Additionally, the Minnesota Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' conduct as described herein as well.

COUNT 23

Montana False Claims Act
(M.C.A. § 17-8-401 *et seq.*)

383. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

384. This is a claim for damages and a civil penalty under the Montana Medicaid False Claims Act.

385. By virtue of the acts described above, Defendants, for the purpose of defrauding the Montana State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Montana a claim knowing the claim to be false within the meaning of M.C.A. § 17-8-402.

386. The Montana State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

387. As a result, Montana State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Montana State Government.

388. Therefore, the Montana State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

389. Additionally, the Montana State Government is entitled to a civil penalty equal to the full amount of the benefit received by Defendants plus triple the amount of damages suffered by the state as a result of the conduct by Defendants as described herein.

COUNT 24

Nevada False Claims Act
(Nev. Rev. Stat. § 357.040(1)(a))

390. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

391. This is a claim for penalties and treble damages under the Nevada False Claims Act, titled "Submission of False Claims to State or Local Government."

392. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Nevada State-funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(a).

393. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Nevada State-funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(b).

394. The Nevada State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

395. As a result, Nevada State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Nevada State Government.

396. Therefore, the Nevada State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

397. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 25

New Hampshire False Claims Act
(N.H. Rev. Stat. Ann. § 167:61-b(I)(a)-(b))

398. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

399. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

400. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New Hampshire State-funded programs to officers or employees of the state within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(a).

401. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Hampshire State-funded programs within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(b).

402. The New Hampshire State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

403. As a result, New Hampshire State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Hampshire State Government.

404. Therefore, the New Hampshire State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

405. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 26

New Jersey False Claims Act
(N.J.S.A. § 2A:32C-1 *et seq.*)

406. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

407. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

408. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Jersey State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Jersey State-funded programs to the State within the meaning of N.J.S.A. § 2A:32C-2.

409. The New Jersey State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

410. As a result, New Jersey State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Jersey State Government.

411. Therefore, the New Jersey State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

412. Additionally, the New Jersey State Government is entitled to the maximum penalty under N.J.S.A. § 2A:32C-3 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 27

New Mexico Medicaid False Claims Act
(N.M. Stat. Ann. § 27-14-4 *et seq.*)

413. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

414. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

415. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State-funded programs to the State within the meaning of N.M. Stat. Ann. § 27-14-4(A).

416. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Mexico State-funded programs within the meaning of N.M. Stat. Ann. § 27-14-4(C).

417. The New Mexico State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

418. As a result, New Mexico State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Mexico State Government.

419. Therefore, the New Mexico State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

420. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 28

New Mexico Fraud Against Taxpayers Act
(N.M.S.A. 1978, § 44-9-1)

421. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

422. This is a claim for penalties and treble damages under the New Mexico Fraud Against Taxpayers Act.

423. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State-funded programs to the State.

424. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false, misleading, or fraudulent records or statements to obtain or support the approval of or the payment on false or fraudulent claims.

425. The New Mexico State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

426. As a result, New Mexico State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New Mexico State Government.

427. Therefore, the New Mexico State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

428. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 29

New York False Claims Act
(N.Y. State Fin. Law § 189(1)(a)-(b))

429. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

430. This is a claim for penalties and treble damages under the New York False Claims Act.

431. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York State-funded programs to officers or employees or agents of the state within the meaning of N.Y. State Fin. Law § 189(1)(a).

432. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York State-funded programs within the meaning of N.Y. State Fin. Law § 189(1)(b).

433. The New York State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

434. As a result, New York State monies were lost through payments made because of the claims, and other costs and losses were sustained by the New York State Government.

435. Therefore, the New York State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

436. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 30

North Carolina False Claims Act
(N.C.G.S.A. § 1-605 *et seq.*)

437. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

438. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

439. By virtue of the acts described above, Defendants, for the purpose of defrauding the North Carolina State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other North Carolina State-funded programs to officers or employees of the state within the meaning of N.C.G.S.A. § 1-606.

440. The North Carolina State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

441. As a result, North Carolina State monies were lost through payments made because of the claims, and other costs and losses were sustained by the North Carolina State Government.

442. Therefore, the North Carolina State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

443. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 31

Oklahoma Medicaid Program Integrity Act
(56 Okl. St. Ann. § 1001 *et seq.*)

444. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

445. This is a claim for penalties and treble damages under the Oklahoma False Claims Act.

446. By virtue of the acts described above, Defendants, for the purpose of defrauding the Oklahoma State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Oklahoma State-funded programs to officers or employees of the state within the meaning of 56 Okl. St. Ann. § 1005.

447. The Oklahoma State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

448. As a result, Oklahoma State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Oklahoma State Government.

449. Therefore, the Oklahoma State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

450. Additionally, the Oklahoma State Government is entitled under 56 Okl. St. Ann. § 1006 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 32

Rhode Island State False Claims Act
(Gen. Laws 1956, § 9-1.1-1)

451. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

452. This is a claim for penalties and treble damages under the Rhode Island State False Claims Act.

453. By virtue of the acts described above, Defendants, for the purpose of defrauding the Rhode Island State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Rhode Island State-funded programs to officers or employees of the state within the meaning of Gen. Laws 1956, § 9-1.1-3.

454. The Rhode Island State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

455. As a result, Rhode Island State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Rhode Island State Government.

456. Therefore, the Rhode Island State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

457. Additionally, the Rhode Island State Government is entitled under Gen. Laws 1956, § 9-1.1-3 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 33

Tennessee False Claims Act
(Tenn. Code Ann. § 4-18-103(a)(1)-(2))

458. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

459. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

460. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented false

claims for payment or approval under Medicaid and other Tennessee State-funded programs to officers or employees of the state within the meaning of Tenn. Code Ann. § 4-18-103(a)(1).

461. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Tennessee State-funded programs within the meaning of Tenn. Code Ann. § 4-18-03(a)(2).

462. The Tennessee State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

463. As a result, Tennessee State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Tennessee State Government.

464. Therefore, the Tennessee State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

465. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 34

Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-182(a)(1)(A)-(B))

466. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

467. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

468. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented to the state

claims for payment under the Medicaid program knowing such claims were false or fraudulent within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(A).

469. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state knowing such record or statement were false within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(B).

470. The Tennessee State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

471. As a result, Tennessee State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Tennessee State Government.

472. Therefore, the Tennessee State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

473. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from Defendants' conduct as described herein.

COUNT 35

Texas Medicaid Fraud Prevention Law
(Tex. Hum. Res. Code § 36.002 *et seq.*)

474. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

475. This is a claim for restitution, interest, penalties and double damages under the Texas Medicaid Fraud Prevention Law.

476. By virtue of the acts described above, Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, and/or caused to be made, false statements or representations of material facts on applications for contracts, benefits, or payments under the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(1)(A).

477. By virtue of the acts described above, Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, caused to be made, induced, and/or sought to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(4)(B).

478. The Texas State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

479. As a result, Texas State monies were lost through payments made because of the false statements or representations, and other costs and losses were sustained by the Texas State Government.

480. Therefore, the Texas State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

481. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by Defendants under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

COUNT 36

Vermont False Claims Act
(32 V.S.A. § 632)

482. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

483. This is a claim for penalties and treble damages under the Vermont False Claims Act.

484. By virtue of the acts described above, Defendants, for the purpose of defrauding the Vermont State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Vermont State-funded programs to officers or employees of the State within the meaning of 32 V.S.A. § 632.

485. By virtue of the acts described above, Defendants, for the purpose of defrauding the Vermont State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Vermont-State-funded programs within the meaning of 32 V.S.A. § 632.

486. The Vermont State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

487. As a result, Vermont State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Vermont State Government.

488. Therefore, the Vermont State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

489. Additionally, the Vermont State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 37

Virginia Fraud Against Taxpayers Act
(Va. Code Ann. § 8.01-216.3(A)(1)-(2))

490. Relator repeats and incorporates all of the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

491. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

492. By virtue of the acts described above, Defendants, for the purpose of defrauding the Virginia Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Virginia Commonwealth-funded programs to officers or employees of the Commonwealth within the meaning of Va. Code Ann. § 8.01-216.3(A)(1).

493. By virtue of the acts described above, Defendants, for the purpose of defrauding the Virginia Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth under Medicaid and other Virginia Commonwealth-funded programs within the meaning of Va. Code Ann. § 8.01-216.3(A)(2).

494. The Virginia Commonwealth Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

495. As a result, Virginia Commonwealth monies were lost through payments made because of the claims, and other costs and losses were sustained by the Virginia Commonwealth Government.

496. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

497. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 38

Washington False Claims Act
(RCW § 48.80.030)

498. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

499. This is a claim for penalties and treble damages under the Washington False Claims Act.

500. By virtue of the acts described above, Defendants, for the purpose of defrauding the Washington State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Vermont State-funded programs to officers or employees of the State within the meaning of RCW § 48.80.030.

501. By virtue of the acts described above, Defendants, for the purpose of defrauding the Washington State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Washington-State-funded programs within the meaning of RCW § 48.80.030.

502. The Washington State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

503. As a result, Washington State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Washington State Government.

504. Therefore, the Washington State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

505. Additionally, the Washington State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 39

Wisconsin Medical Assistance False Claims Act
(W.S.A. §§ 49.485, 49.49)

506. Relator repeats and incorporates all the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

507. This is a claim for penalties and treble damages under the Wisconsin Medical Assistance False Claims Act.

508. By virtue of the acts described above, Defendants, for the purpose of defrauding the Wisconsin Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State under Medicaid and other Wisconsin State-funded programs within the meaning of W.S.A. §§ 49.485, 49.49.

509. The Wisconsin State Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

510. As a result, Wisconsin State monies were lost through payments made because of the claims, and other costs and losses were sustained by the Wisconsin State Government.

511. Therefore, the Wisconsin State Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

512. Additionally, the Wisconsin State Government is entitled under to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from Defendants' conduct as described herein.

COUNT 40

Chicago False Claims Act
(Chicago Mun. Code Ch. 1-22-020(1)-(2))

513. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

514. This is a claim for penalties and treble damages under the Chicago False Claims Act.

515. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Chicago City-funded programs to officers or employees of the City within the meaning of Chicago Mun. Code Ch. 1-22-020(1).

516. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly made, used, and/or caused to be made or used, false records or statement to get false claims paid or approved under Medicaid and other Chicago City-funded programs within the meaning of Chicago Mun. Code ch. 1-22-020(2).

517. The Chicago City Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

518. As a result, Chicago City monies were lost through payments made because of the claims, and other costs and losses were sustained by the Chicago City Government.

519. Therefore, the Chicago City Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

520. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

COUNT 41

New York City False Claims Act
(NYC Admin. Code § 7-803(a)(1))

521. Relator repeats and incorporates the preceding paragraphs of the Second Amended Complaint as if fully set forth herein.

522. This is a claim for penalties and treble damages under the New York City False Claims Act.

523. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York City-funded programs to officers or employees of the City within the meaning of NYC Admin. Code § 7-803(a)(1).

524. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York City Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York City-funded programs within the meaning of NYC Admin. Code § 7-803(a)(2).

525. The New York City Government, unaware of the falsity, paid claims that it would not have paid had it known of Defendants' practices.

526. As a result, New York City monies were lost through payments made because of the claims, and other costs and losses were sustained by the New York City Government.

527. Therefore, the New York City Government has been damaged in an amount to be proved at trial and is entitled to treble damages as permitted by statute.

528. Additionally, the New York City Government is entitled to the maximum penalty of $15,000 for each and every false claim presented and caused to be presented by Defendants and arising from their conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for the following relief:

A. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the United States, plus a civil penalty of up to $10,000 for each violation of 31 U.S.C. § 3729 proved at trial;

B. Judgment in amount of proven damages at trial for payment in mistake of fact and unjust enrichment;

C. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of California, plus a civil penalty of $10,000 for each violation of Cal. Gov't Code § 12651 proved at trial;

D. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Colorado, plus a penalty of $10,000 for each violation of the Colorado False Claims Act, C.R.S.A § 25.5-4-304, as well as costs as permitted under the statute;

E. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Connecticut, plus a penalty of $10,000 for each violation of the Connecticut State funded programs within the meaning of C.G.S.A § 17b-301(a) and 301(b), as well as costs as permitted under the statute;

F. Judgment in an amount equal to treble damages to be proved at trial against Defendants and in favor of the State of Delaware, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201 proved at trial;

G. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the District of Columbia, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14 proved at trial;

H. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Florida, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082 proved at trial;

I. Judgment in an amount equal to threefold the damages to be proved at trial against Defendants and in favor of the State of Georgia, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. § 49-4-168.1 proved at trial;

J. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Hawaii, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21 proved at trial.

K. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3 proved at trial;

L. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proved at trial;

M. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Iowa, plus a civil penalty of at least $10,000 for each violation of the Iowa False Claims Act proved at trial as well as costs as permitted by statute;

N. Judgment in an amount equal to the damages to be proved at trial against Defendants and in favor of the State of Louisiana, plus a civil fine in the amount of three times the amount of actual damages sustained for each violation of La. Rev. Stat. 46:438.3 proved at trial;

O. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Maryland;

P. Judgment in an amount equal to threefold the damages to be proved at trial against Defendants and in favor of the Commonwealth of Massachusetts, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12, § 5B proved at trial;

Q. Judgment in an amount equal to the damages to be proved at trial against Defendants and in favor of the State of Michigan, plus a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state for each violation of Mich. Comp. Laws § 400.610a proved at trial;

R. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Minnesota, plus a civil penalty of $10,000 for each violation of Minn. Stat § 15C.01 proved at trial;

S. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Montana;

T. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Nevada, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040 proved at trial;

U. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of New Hampshire, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I) proved at trial;

V. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of New Jersey, plus a civil penalty of $10,000 for each violation of N.J.S.A. § 2A:32C-2 proved at trial;

W. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. § 27-14-4 and N.M. Stat. Ann. 1978 § 44-9-1 proved at trial;

X. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of New York, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. Law § 189 proved at trial;

Y. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of North Carolina, plus a civil penalty of $11,000 for each violation of N.C.G.S.A. § 1-606 proved at trial.

Z. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proved at trial pursuant to 56 Okl. St. Ann. §1006;

AA. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proved at trial pursuant Gen. Laws 1956, § 9-1.1-3;

BB. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § Tenn. Code Ann. § 4-18-103 proved at trial;

CC. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182 proved at trial;

DD. Judgment in an amount equal to restitution, interest, and two times the damages to be proved at trial against Defendants and in favor of the State of Texas, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002 proved at trial;

EE. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Vermont, plus a civil penalty of $11,000 for each violation of 32 V.S.A. § 632 proved at trial;

FF. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3 proved at trial;

GG. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Washington, plus a civil penalty of $11,000 for each violation of Washington-State-funded programs within the meaning of RCW § 48.80.030 proved at trial.

HH. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the State of Wisconsin plus a civil penalty of $10,000 for each violation proved at trial pursuant W.S.A. §§ 49.485; 49.49;

II. Judgment in an amount equal to treble the damages to be proved at trial against Defendants and in favor of the City of Chicago, plus a civil penalty of $10,000 for each violation of Chicago Mun. Code ch. 1-22-020 proved at trial;

JJ. Judgment in an amount equal to threefold the damages to be proved at trial against Defendants and in favor of the City of New York, plus a civil penalty of $15,000 for each violation of NYC Admin. Code § 7-803 proved at trial;

KK. An award to Relator of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees;

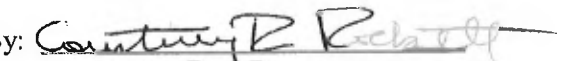
LL. All such other, further and different relief, whether preliminary or permanent, legal, general or equitable, as the Court deems just and proper.

JURY DEMAND

Relator hereby demands a trial by Jury in this matter.

Respectfully submitted,

BOIES SCHILLER FLEXNER LLP

By: 

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