IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

UNDER SEAL, Civil Action No.

Plaintiff[s],

JURY TRIAL DEMANDED

v.

UNDER SEAL, FILED IN CAMERA AND UNDER

Defendant[s]. SEAL PURSUANT TO 31 U.S.C. § 3730

COMPLAINT

SEALED CASE---DO NOT ENTER ON PACER

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UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, WISCONSIN, the COMMONWEALTHS OF MASSACHUSETTS, PUERTO RICO, AND VIRGINIA, and the DISTRICT OF COLUMBIA, *ex rel.* JOHN DOES 1, 2, and 3,

Plaintiffs,

v.

CARDINAL HEALTH, INC., CARDINAL HEALTH SPECIALTY SOLUTIONS GROUP, CARDINAL HEALTH 108, LLC, CARDINAL HEALTH 118, LLC, TENNESSEE ONCOLOGY, PLLC, CALIFORNIA CANCER ASSOCIATES FOR RESEARCH AND EXCELLENCE, INC., BIRMINGHAM HEMATOLOGY AND ONCOLOGY ASSOCIATES, LLC, ONCOLOGY SPECIALISTS, PC, TENNESSEE CANCER SPECIALISTS, PLLC, SOUTH CAROLINA ONCOLOGY ASSOCIATES, PA, DAYTON PHYSICIANS, LLC, MICHIGAN HEALTHCARE PROFESSIONALS, PC, COLUMBUS ONCOLOGY ASSOCIATES, INC., AMERICAN ONCOLOGY PARTNERS, PA, MID-OHIO ONCOLOGY/HEMATOLOGY, INC., OHIO ONCOLOGY & HEMATOLOGY, LLC, NORTHWEST MEDICAL SPECIALTIES, PLLC, CANCER CARE NORTHWEST CENTERS, PS, MONTEREY BAY ONCOLOGY CORP., HEALTH FIRST MEDICAL, LLC, PLLC, BAYER CORP., EXELISIS, INC., AMGEN USA, INC. AMGEN, INC., TAKEDA PHARMACEUTICALS AMERICA. INC. and MILLENIUM PHARMACEUTICALS. INC.,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

COMPLAINT FOR VIOLATIONS OF THE FEDERAL AND STATE FALSE CLAIMS <u>ACTS</u>

I. <u>INTRODUCTION</u>

1. This is an action brought on behalf of the United States of America and certain States (the "States" or "*Qui Tam* States") pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. (the "FCA" or the "Federal FCA"), and the state false claims act statutes identified herein ("State *Qui Tam* statutes" or "State FCAs"), to recover damages, civil penalties, and other relief for false and/or fraudulent statements, records, and claims made and caused to be made to Government Health Care Programs such as Medicare and Medicaid, and for retained overpayments, and for conspiring to violate these statutes, by the Defendants and/or their agents, employees and subsidiaries.

A. The Fraudulent Schemes

- 2. Relators bring this action to challenge several illegal schemes perpetrated by Defendants Cardinal Health, Inc. and its subsidiaries, in conjunction with the Medical Practice Defendants and the Pharmaceutical Manufacturer Defendants.
- 3. Defendant Cardinal Health, Inc. ("Cardinal" or "Cardinal Health"), is a drug wholesaler and medical supplier with annual revenues of more than \$136 billion. Through its Specialty Pharmaceutical Distribution ("SPD") and VitalSource GPO (Group Purchasing Organization) and other wholly owned subsidiaries, it sells and distributes specialty pharmaceuticals, generating the nearly \$4 billion in annual revenue.
- 4. "Specialty pharmaceuticals" are expensive biological drugs that require special handling and are prescribed for serious diseases including cancer. The products at issue here are developed and manufactured by pharmaceutical manufacturing companies. Manufacturers

market specialty pharmaceuticals directly to providers but the product is shipped/distributed through wholesalers/distributors such as Cardinal.

- 5. The fraudulent schemes at issue here involve the marketing, sale, and distribution of specialty pharmaceuticals to community oncology and urology physician practices, *i.e.*, physician practices outside of hospitals or nursing homes. The drugs administered by these practices are reimbursed by Government Health Care Programs such as Medicare and Medicaid.
- 6. As described more fully below, Cardinal created an "ecosystem" of strategies to incentivize providers to switch to Cardinal and to switch from generic to branded drug products which cost the government and patients more but are far more lucrative for Cardinal. These strategies were all interrelated, designed with the ultimate goal of increasing the profit to SPD and VitalSource GPO.
- 7. Cardinal Health offered kickbacks, often months or years in advance of any drug purchases, to induce providers to enter exclusive distribution deals. Cardinal recognized that the timing of payments to providers was a critical ingredient to gaining market share. By converting legal rebates (*i.e.*, refunds that are made *after* the purchase of the drugs) into illegal upfront "prebates" and "signing bonuses," SPD put cash in the hands of providers immediately, providing them a financial "float," making SPD a more attractive vendor than its competitors.
- 8. Each contract signed by a provider committed it to purchasing 95% of its branded and generic pharmaceutical products from SPD. The agreements also contained claw-back provisions which provided a potentially devastating financial deterrent to contract termination.

 The combination of the cash float "carrot" with the claw back "stick" effectively converted contracts terminable on ninety days written notice into binding multi-year commitments. Further,

because of how these payments were calculated, these arrangements effectively prevented providers from wholesale switching to cheaper (typically non-branded) drugs.

- 9. To date, the Cardinal Health Defendants have unlawfully paid tens of millions of dollars to providers upfront in exchange for binding commitments to purchase billions of dollars of specialty drugs exclusively from them instead of through rival suppliers. Providers receiving kickbacks have in turn submitted billions of dollars in claims annually to Government Health Care Programs that include the cost of these drugs.
- 10. Cardinal Health successfully leveraged this ecosystem of tactics into a massive capture of market share. Between 2012 and 2018, Cardinal Health increased its community pharmaceutical distribution volume from less than \$400 million to almost \$4 billion and Cardinal's market share in the community oncology distribution business, relative to its competitors, went from less than 5% in 2012 to 20% at the end of 2018.
- 11. Further, the illegal signing bonuses, prebates, and other incentives such as so-called "off-invoice discounts" described below, meant that the practices paid less for the drug than the sales price reported by the manufacturer to Medicare for calculation in Average Sales Price ("ASP"). SPD was able to offer these discounts because it received distributor service fees from the manufacturers (in return for its services in distributing the drugs) that are excluded from the manufacturer's ASP calculation. However, these fees were not, in fact, *bona fide* service fees eligible for exemption from ASP because they were passed on to practices in the form of discounts. This scheme, therefore, fraudulently inflated the ASP of the drug, increasing the profit to providers who were reimbursed at 106% of the inflated ASP and causing the government to pay more for the drug to all providers.

- 12. GPOs are buying consortiums or associations of healthcare providers designed to aggregate the purchasing power of members to drive down drug acquisition costs. They negotiate pricing with manufacturers, but do not purchase any drug product themselves. GPOs are expected to be independent of the vendors with whom they negotiate contracts, however, in the specialty pharmaceutical market, GPOs are captive entities wholly-owned and controlled by distributors, and membership in a particular GPO locks a provider into exclusive use of the affiliated specialty distributor. For example, VitalSource GPO set pricing solely for drugs distributed by SPD. Likewise, a provider contracting with VitalSource was locked into purchasing from SPD.
- 13. While GPOs are expected to act in the interest of their members and drive down drug acquisition costs, VitalSource GPO was corrupted by Cardinal Health to serve its profit interest. This interest took several relevant forms:
 - a. Because branded drug manufacturers pay more to VitalSource GPO and SPD than do generic manufacturers, VitalSource utilized its position to push providers to increase the market share and revenue for branded drugs.
 Moreover, the higher prices of branded drugs compared with generics doubly benefited Cardinal because the same volume of drugs generated higher service fees for VitalSource GPO and SPD. VitalSource worked with pharmaceutical manufacturers to offer providers "product share" or "switching" contracts that rewarded providers for achieving particular market share milestones.
 "Switching" contracts are suspect under the Anti-Kickback Statute and do not qualify under the discount/rebate safe harbor.

- b. SPD utilized VitalSource GPO to funnel free services to providers to induce them to enter into exclusive distribution contracts with SPD. These services included access to complex software programs and expert legal, regulatory, and administrative consultants including licensed pharmacists, which enable providers (i) to establish and operate highly profitable in-practice pharmacies as well as (ii) choose treatment protocols for patients that maximized practice discounts and rebates. Defendants offered these services—which providers would otherwise have to pay for —as kickbacks to induce the practices to enter exclusive distribution deals and funneled them through VitalSource to avoid AKS scrutiny.
- c. VitalSource GPO was paid additional money by pharmaceutical manufacturers to help them market their product to providers. VitalSource GPO received millions of dollars to set up "strategic planning meetings" and "in practice meetings" between manufacturers and GPO member providers, all with the explicit purpose of influencing the purchasing behavior of its large-volume members. To induce the members' attendance at these marketing presentations, VitalSource gave them valuable data analyses not offered to smaller members.
- 14. Cardinal Health knew Government Health Care programs would ultimately pay for a large portion of its specialty pharmaceuticals sold through the use of these various forms of kickbacks. Cardinal Health knew also that Government Health Care Programs will not pay claims tainted by kickbacks of this sort. As such, Cardinal Health is liable under the Federal and State FCAs for knowingly causing providers to submit false certifications of compliance with the

AKS and to submit false or fraudulent claims to get government funds paid or approved by the United States and the States.

B. The Instant Action

- 15. Based on the Federal FCA provisions, and comparable provisions of the State FCAs, *qui tam* Plaintiffs-Relators seek, through this action, to recover damages and civil penalties arising from the Defendants' knowing fraud against the United States and the States. Defendants have paid millions of dollars in bribes and induced billions of dollars in false or fraudulent claims to the Government since at least 2012.
- 16. The allegations set forth in this Complaint have not been publicly disclosed within the meaning of the Federal FCA, as amended, 31 U.S.C. § 3730(e)(4), or analogous provisions of the State FCAs. In the alternative, if the Court finds that there was a public disclosure of such allegations before the filing of this Complaint, Relators are an "original source" as that term is used in the Federal and State FCAs. *Id*.
- 17. Prior to the filing of this Complaint, Relators made substantive disclosures to the Government of facts and evidence underlying the allegations in this Complaint.
- 18. This action is filed *in camera* and under seal pursuant to the requirements of the federal and state false claims acts.

II. JURISDICTION AND VENUE

19. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345, and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court has original and supplemental jurisdiction over the State law claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367 because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence as the claims brought on behalf of the United States under 31 U.S.C. § 3730.

- 20. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because one or more Defendants can be found in, resides in, and transacts substantial business in this district, including business related to Defendants' misconduct.
- 21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391, and 28 U.S.C. § 1395(a), because Defendant Cardinal Health transacts business in this District by supplying providers with prescription drugs.

III. PARTIES

22. Plaintiffs the United States of America and the *Qui Tam* States are the real parties in interest with respect to the federal and state False Claims Act *qui tam* claims herein. Plaintiffs-Relators are prosecuting this action on the real parties' behalf pursuant to 31 U.S.C. § 3730(b) and comparable provisions of the State FCAs.

A. Relators

- 23. Relator John Doe 1 is a resident and citizen of the United States who is familiar with and has knowledge of the Defendants' business operations and the allegations herein.

 Relator's identity and additional information regarding Relator's knowledge of the allegations herein have been and will continue to be provided to the government pursuant to the Federal and State FCAs.
- 24. Relator John Doe 2 is a resident and citizen of the United States who is familiar with and has knowledge of the Defendants' business operations and the allegations herein.

 Relator's identity and additional information regarding Relator's knowledge of the allegations herein have been and will continue to be provided to the government pursuant to the Federal and State FCAs.
- 25. Relator John Doe 3 is a resident and citizen of the United States who is familiar with and has knowledge of the Defendants' business operations and the allegations herein.

Relator's identity and additional information regarding Relator's knowledge of the allegations herein have been and will continue to be provided to the government pursuant to the Federal and State FCAs.

B. The Cardinal Health Defendants

- 26. Defendant Cardinal Health, Inc. is a drug wholesaler and medical supplier incorporated in 1979 in Ohio. It is headquartered at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health is a Fortune 16 company, with annual revenues of more than \$136 billion.
- 27. Defendant Cardinal Health Specialty Solutions Group ("Cardinal Specialty Solutions") is a subsidiary of Defendant CHI. Cardinal Specialty Solutions is headquartered at 7000 Cardinal Place, Dublin, Ohio 43017. The majority of Cardinal Specialty Solutions' nearly \$20 billion annual revenue derives from its Provider Solutions Business Unit that is engaged in selling and distributing specialty pharmaceuticals. The Provider Solutions Business Unit includes Defendants Specialty Pharmaceutical Distribution and VitalSource GPO.
- 28. Defendant Cardinal Health 108, LLC, d/b/a Specialty Pharmaceutical Distribution ("SPD"), is a subsidiary of Cardinal Specialty Solutions. SPD is organized in Delaware and headquartered at 7000 Cardinal Place, Dublin, Ohio 43017. SPD is responsible for the distribution of specialty pharmaceuticals. It generates approximately \$13 billion annually, of which \$3.5 billion derives from sales to community oncology practices.
- 29. Defendant Cardinal Health 118, LLC d/b/a VitalSource GPO ("VitalSource GPO"), is a subsidiary of Cardinal Health that is operated by Cardinal Specialty Solutions. VitalSource GPO is a limited liability company organized in Delaware and headquartered at 7000 Cardinal Place, Dublin, Ohio 43017. It is responsible for negotiating prices on behalf of provider members with drug suppliers and manufacturers in exchange for administrative service fees. It generates approximately \$40 million annually with a profit margin in excess of 75%.

30. Defendants Cardinal Health, Inc., Cardinal Specialty Solutions, SPD, and VitalSource will be referred to collectively as "Cardinal Health" and/or the "Cardinal Health Defendants."

C. The Medical Practice Defendants

- 31. Defendant Tennessee Oncology, PLLC ("Tennessee Oncology") is a professional limited liability company organized in 1996 in Tennessee. It is headquartered at 2004 Hayes St., Nashville, Tennessee, 37203. Tennessee Oncology is a community-based oncology practice with over 35 locations throughout Tennessee. It was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since late 2014. Tennessee Oncology received illegal kickbacks including prebates worth nearly \$11 million dollars between 2015 and 2019, and a signing bonus of over \$620,000. Tennessee Oncology purchased approximately \$500 million in specialty pharmaceuticals from SPD annually. Tennessee Oncology also accepted valuable free data analysis from VitalSource in exchange for attending at least two marketing meetings with Pharmaceutical Manufacturer Defendants in 2017.
- 32. Defendant California Cancer Associates for Research and Excellence, Inc. ("cCARE"), was incorporated in 1993 in California and is headquartered at 1510 E. Herndon Ave., Suite 310, Fresno, California 93720. cCARE claims to be the largest full-service, private oncology and hematology practice in California, with locations in San Diego and Fresno. cCARE was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2016. cCARE received illegal kickbacks including prebates worth at least \$2.4 million between 2015 and 2019 and a signing bonus of \$203,000. cCARE purchased approximately \$120 million in specialty pharmaceuticals from SPD annually.
- 33. Defendant Birmingham Hematology and Oncology Associates, LLC, d/b/a
 Alabama Oncology ("Alabama Oncology"), is a limited liability company organized in 1999 in

Alabama. Its registered agent is located at 810 St. Vincent Dr., Birmingham, Alabama 35205. Alabama Oncology is a community-based oncology practice with nine locations in the Birmingham, Alabama area. Alabama Oncology was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2016. Alabama Oncology received illegal kickbacks including prebates worth at least \$3.36 million between 2014 and 2019 and a signing bonus of \$151,000. Alabama Oncology purchased approximately \$160 million in specialty pharmaceuticals from SPD annually.

- 34. Defendant Oncology Specialties, PC, d/b/a Clearview Cancer Institute ("Clearview Cancer"), is a domestic professional corporation organized in 1985 in Alabama. Its registered agent is located at 3601 CCI Dr. NW, Huntsville, Alabama 35805. Clearview Cancer is a community-based oncology and hematology practice with nine locations throughout northern Alabama. Clearview Cancer was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2015. Clearview Cancer received illegal kickbacks including a signing bonus of \$1.5 million. Clearview Cancer purchased approximately \$200 million in specialty pharmaceuticals from SPD annually.
- 35. Defendant Tennessee Cancer Specialists, PLLC ("Tennessee Cancer Specialists") is a professional limited liability company organized in 2004 in Tennessee. It is headquartered at 900 E Hill Ave., Suite 230, Knoxville, Tennessee 37915. Tennessee Cancer Specialists claims to be the third largest community-based oncology and hematology practice in Tennessee, with fourteen locations. Tennessee Cancer Specialists was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2016. Tennessee Cancer Specialists received illegal kickbacks including prebates worth at least \$4.4 million between 2015 and 2021

and a signing bonus of \$285,000. Tennessee Cancer Specialists purchased approximately \$170 million in specialty pharmaceuticals from SPD annually.

- 36. Defendant South Carolina Oncology Associates, PA ("South Carolina Oncology") was organized in 1990. Its registered agent is located at 166 Stoneridge Dr., Columbia, South Carolina 29210. South Carolina Oncology is a comprehensive cancer treatment center in South Carolina. South Carolina Oncology was a member of VitalSource GPO and granted SPD exclusive distribution rights since at least 2016. South Carolina Oncology received illegal kickbacks including prebates worth at least \$2.52 million between 2014 and 2019 and a signing bonus of \$150,000. South Carolina Oncology purchased approximately \$140 million in specialty pharmaceuticals from SPD annually. South Carolina Oncology also accepted valuable free data analysis from VitalSource in exchange for attending at least one marketing meeting with Pharmaceutical Manufacturer Defendants in 2017 and planning to attend others.
- 37. Defendant Dayton Physicians, LLC, d/b/a Dayton Physicians Network ("Dayton Physicians"), is a limited liability company organized in 2005 in Ohio. Its registered agent is located at 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. Dayton Physicians is a community-based oncology, hematology, and urology practice with seven oncology and hematology locations in southwestern Ohio. Dayton Physicians was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2017. Dayton Physicians received illegal kickbacks including a signing bonus of \$1 million. Dayton Physicians purchased approximately \$100 million in specialty pharmaceuticals from SPD annually. Dayton Physicians also accepted valuable free data analysis from VitalSource in exchange for attending at least one marketing meeting with Pharmaceutical Manufacturer Defendants in 2017 and planning to attend others in 2018.

- 38. Defendant Michigan Healthcare Professionals, PC ("Michigan Healthcare"), is a professional service corporation organized in 2011 in Michigan. It is registered at 30000 Northwestern Hwy., Farmington Hills, Michigan 48334. Michigan Healthcare claims to be "a physician led and administered organization" with over 400 Michigan physicians offering a wide range of specialties, including oncology care. Michigan Healthcare was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2017. Michigan Healthcare received illegal kickbacks including a signing bonus of \$2.34 million. Michigan Healthcare purchased approximately \$125 million in specialty pharmaceuticals from SPD annually.
- 39. Defendant "Ohio Oncology" is a group of related health care entities that purchases drugs together from Cardinal Health Defendants. Ohio Oncology was a member of VitalSource GPO and granted SPD exclusive distribution rights since at least 2017. Ohio Oncology received illegal kickbacks including prebates worth at least \$1.62 million between 2015 and 2020 and a signing bonus of \$92,000. Ohio Oncology purchased approximately \$90 million in specialty pharmaceuticals from SPD annually. Ohio Oncology planned to accept valuable free data analysis from VitalSource in exchange for attending at least one marketing meeting with Pharmaceutical Manufacturer Defendants in 2018. Ohio Oncology includes:
 - a. Defendant Columbus Oncology Associates, Inc., d/b/a Columbus Oncology & Hematology Associates, a medical company incorporated in 1987 in Ohio. Its registered agent is located at 810 Jasonway Ave., Suite A, Columbus, Ohio 43214. It is a community-based oncology and hematology practice.
 - b. Defendant American Oncology Partners, PA, d/b/a Zangmeister Cancer
 Center, a professional association organized in 2018 in Florida. Its registered

- agent is located at 1200 South Pine Island Road, Plantation, Florida 33324; it has an Ohio branch registered at 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. Zangmeister Cancer Center is a community-based oncology and hematology practice with two locations in Ohio.
- c. Defendant Mid-Ohio Oncology/Hematology, Inc., is a medical company incorporated in Ohio in 1985. Its registered agent is located at 3100 Plaza Properties Blvd., Columbus, Ohio 43219. It is the pharmacy for Zangmeister Cancer Center.
- d. Defendant Ohio Oncology & Hematology, LLC, is limited liability company organized in 2012 in Ohio. Its registered agent, like Zangmeister Cancer Center, is located at 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. Its president, Patrick C. Elwood, is a practicing physician at Zangmeister Cancer Center. Its practice, like Columbus Oncology & Hematology Associates, is located at 810 Jasonway Ave., Suite A, Columbus, Ohio 43214.
- 40. Defendant Northwest Medical Specialties, PLLC ("Northwest Medical"), is a professional limited liability company organized in 1997 in Washington. It is headquartered at 1624 South I Street, Suite 305, Tacoma, Washington 98405. Northwest Medical is a community-based practice specializing in oncology, hematology, and infectious disease, with five locations throughout Washington state. Northwest Medical was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since at least 2017. Northwest Medical received illegal kickbacks including a signing bonus of \$1.2 million. Northwest Medical purchased approximately \$100 million in specialty pharmaceuticals from SPD annually.

- 41. Defendant Cancer Care Northwest Centers, P.S. ("Cancer Care Northwest") is a professional service corporation organized in 1977 in Washington. It is registered at 1204 North Vercler Rd., Spokane Valley, Washington, 99216. Cancer Care Northwest claims to be the "Inland Northwest's premier cancer center" for cancer and blood-related diseases, with over 8 locations throughout the greater Spokane area. It was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since mid-2015. Cancer Care Northwest received illegal kickbacks including prebates worth at least \$360,000 between 2016 and 2019. Cancer Care Northwest purchased approximately \$30 million in specialty pharmaceuticals from SPD annually.
- 42. Defendant Monterey Bay Oncology, a Medical Corporation, d/b/a Pacific Cancer Center ("Pacific Cancer Center"), is a company incorporated in 1996 in California. It is registered at 5 Harris Ct., Bldg. T, Suite 201, Monterey, California, 93940. Pacific Cancer Center is a community-based oncology and hematology practice. It was a member of Defendant VitalSource GPO and granted SPD exclusive distribution rights since early 2015. Pacific Cancer Center received illegal kickbacks including prebates worth at least \$350,000 between 2015 and 2019. Pacific Cancer Center purchased over \$27 million in specialty pharmaceuticals from SPD annually.
- 43. Defendant Health First Medical Group, LLC ("Health First Medical Group") is a limited liability company organized in 2012 in Florida. It has an agent registered at 6450 U.S. Highway 1, Rockledge, Florida 32955. Health First Medical Group claims to be the "largest multi-specialty physician group on the Space Coast" of Florida; its physician members include oncology specialists. It was a member of Defendant VitalSource GPO and granted SPD

exclusive distribution rights since late 2015. Health First Medical Group received illegal kickbacks including prebates worth at least \$200,000 between 2015 and 2018.

D. The Pharmaceutical Manufacturer Defendants

- 44. Defendant Bayer Corp. ("Bayer") is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Bayer is the American subsidiary of Bayer AG, a multinational chemical and pharmaceutical manufacturer headquartered in Leverkusen, Germany with about \$30 billion in annual pharmaceutical revenues. Bayer manufactures and markets prescription products, including "specialty therapeutics in the areas of oncology, hematology and ophthalmology." Bayer paid Defendant VitalSource GPO to hold marketing meetings with large providers to induce referrals of its product Xofigo in violation of the Anti-Kickback Statute. VitalSource provided those providers with valuable data analysis among other things to induce them to attend the marketing meeting.
- 45. Defendant Exelixis, Inc. ("Exelixis") is a Delaware corporation headquartered at 1851 Harbor Bay Pkwy., Alameda, California 94502. Exelisis is a pharmaceutical manufacturer with about \$215 million in annual revenues. Exelixis paid Defendant VitalSource to hold marketing meetings with large providers to induce referrals of its product Cabometryx in violation of the Anti-Kickback Statute. VitalSource provided those providers with valuable data analysis among other things to induce them to attend the marketing meeting.
- 46. Defendant Takeda Pharmaceuticals America, Inc. ("Takeda") is a Delaware corporation with its principal place of business at 1 Takeda Pkwy., Deerfield, Illinois 60015. Takeda is the American subsidiary of Takeda Pharmaceuticals Company Ltd., a multinational pharmaceutical manufacturer headquartered in Tokyo, Japan with about \$16 billion in annual pharmaceutical revenues. Takeda paid Defendant VitalSource GPO to hold marketing meetings with large providers to induce referrals of its product Ninlaro in violation of the Anti-Kickback

Statute. VitalSource provided those providers with valuable data analysis among other things to induce them to attend the marketing meeting.

- 47. Defendant Millennium Pharmaceuticals, Inc. ("Millennium Pharmaceuticals") is an American biopharmaceutical company primarily engaged in the development and commercialization of drug therapies designed for use in the areas of oncology and inflammation. It is headquartered in Cambridge, Massachusetts and a subsidiary of Defendant Takeda Oncology Company. Millennium Pharmaceuticals conducts business throughout the United States (including New York) and in many other countries. It was one of the co-developers of Velcade® (bortezomib) ("Velcade"), approved by the FDA in 2003 for the treatment of patients with multiple myeloma who have received at least two prior therapies, in 2005 for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy, and in 2008 for the initial treatment of patients with multiple myeloma. Since 2003, Millennium Pharmaceuticals has been responsible for the distribution and marketing of Velcade in the United States. In 2012, sales of Velcade totaled more than \$2.3 billion. Millennium and VitalSource GPO utilized illegal switching agreements to induce sales of Velcade.
- 48. Defendant Amgen USA, Inc. ("Amgen USA") operates as a subsidiary of Defendant Amgen, Inc. ("Amgen"). Amgen, a Fortune 500 company, is a publicly-traded diversified, human therapeutics company in the biotechnology industry. Its principal place of business is Thousand Oaks, California. Amgen engages in the discovery, development, manufacture, and delivery of biotherapeutics (*e.g.*, prescription drugs) for various medical needs. The company provides products for the treatment of various human ailments, including anemia, arthritis, psoriasis, cancer treatment side effects, and side effects of dialysis. Three of its largest

selling drugs are XGEVA, Neulasta, and Aransesp. In 2018, Medicare paid over \$1.7 billion for those three products.

- 49. Amgen expressly linked the amount of Administrative Service Fees (ASF) it would pay to VitalSource GPO to the market share that its drugs enjoyed among VitalSource's GPO members. For example, at one point, Amgen increased the ASF it paid on Aranesp and Neulasta from 1% to 2% (which equated to an additional \$1 million per year of profit for VitalSource) as a reward for the market share of its drugs exceeding 10%. In addition, Amgen and VitalSource engaged in a successful campaign to switch GPO members to XGEVA from competitor drugs including generic Pamidronate.
- 50. Amgen also paid Defendant VitalSource to hold marketing meetings with large providers in violation of the Anti-Kickback Statute. VitalSource provided those providers with valuable data analysis to induce them to attend the marketing meeting.

IV. <u>APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS</u> A. Government Health Insurance Programs

- 51. The Health Insurance for the Aged and Disabled Program, known as Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare"), is a health insurance program administered by the United States Government and funded by taxpayer revenue. The United States Department of Health and Human Services ("HHS"), through its Centers for Medicare and Medicaid Services ("CMS"), oversees Medicare.
- 52. Medicare was designed to be a health insurance program and to provide for payment of, among other things, medical services and equipment to persons over 65 years of age and certain others who qualify under Medicare's terms and conditions. The Medicare program has four parts: Part A, Part B, Part C, and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care.

See 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. See 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

- 53. The Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid"), is a health insurance program administered by the United States

 Government and the States and is funded jointly by state and federal taxpayer revenue. CMS and HHS oversee Medicaid jointly with agencies in each State. Each named Plaintiff State participates in Medicaid.
- 54. Medicaid is designed to assist participating States in providing medical services, medical equipment, and prescription drugs to needy individuals. The States and the United States share reimbursement costs. States directly pay providers, and then obtain the federal contribution from accounts drawn on the United States Treasury. 42 C.F.R. §§ 430.0, *et seq.* Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, co-payments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary Program, 42 U.S.C. § 1396d(p)(1), the Specified Low-Income Medicare Beneficiary Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals Program, 42 U.S.C. § 1396d(s). Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (e.g., with Medicare or private insurance providing primary coverage). Medicaid sets

forth minimum requirements for state Medicaid programs to qualify for federal funding; each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

- 55. The Civilian Health and Medical Program of the United States (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. TRICARE pays for, among other things, prescription drugs for its beneficiaries. CHAMPVA, administered by the United States Department of Veterans Affairs ("VA"), is a health care program for the families of veterans with 100-percent service-connected disability, or for those who died from a VA-rated-service-connected disability.
- 56. The federal government operates hospitals, including through its Departments of Defense and VA, and receives and uses federal funds to provide medication to patients treated at these facilities and otherwise, as well as outpatient services. A network of already established VA hospitals and services make up the VA health care system.
- 57. The Federal Employee Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. It pays for, among other things, prescription drugs for its beneficiaries. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government. As a result, fraud on a patient covered by the FEHBP constitutes fraud on the federal government and the loss of federal funds.
- 58. The Office of Workers' Compensation Programs ("OWCP") of the U.S.

 Department of Labor ("DOL") administers federal workers' compensation programs under four

statutes: (1) the Federal Employees' Compensation ("FECA"), 5 U.S.C. §§ 8101, et seq.; (2) the Longshore and Harbor Workers' Compensation Act ("LHWCA"), 33 U.S.C. §§ 901, et seq.; (3) the Federal Black Lung Benefits Act ("FBLBA"), 30 U.S.C. §§ 901, et seq.; and (4) the Energy Employees Occupational Illness Compensation Program Act ("EEOIC") (also known as the "Beryllium Exposure Compensation Act"), 42 U.S.C.A. §§ 7384, et seq.

- 59. The largest of these workers' compensation programs is the FECA program, which provides coverage for approximately three million federal and postal workers for employment-related injuries and occupational diseases. Under the provisions of FECA, OWCP authorizes payment for medical services, including prescription drugs, and establishes limits on the maximum payment for such services.
- 60. Together, the programs described above, and any other government-funded healthcare programs, are referred to as "Government Health Care Programs."
- 61. Physicians and hospitals enter into Provider Agreements with CMS to establish their eligibility to seek Medicare reimbursements. As part of those agreements, the provider must sign the following certification:

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

Form CMS-855I, at 25 (emphasis added) (for physicians and non-physician practitioners); *see* CMS-855A, at 48 (similar for institutional providers); State Medicaid programs require similar certifications.

- 62. Claims submitted by providers to Government Health Care Programs contain similar representations and certifications. *See, e.g.*, Forms CMS-1500 (paper provider claim form used for Medicare and Medicaid). When submitting a claim for payment, a provider does so subject to and under the terms of his certification to the United States that the services were delivered in accordance with federal law, including, compliance with the federal and state anti-kickback statutes. Government Health Care Programs require compliance with these certifications as a material condition of payment, and claims that violate these certifications are false or fraudulent claims under the False Claims Act. CMS, its fiscal agents, and relevant State health agencies will not pay claims for services provided in violation of relevant state or federal laws including the federal and state anti-kickback statutes.
- 63. When submitting a claim for services under Government Health Care Programs, the provider designates a numeric code assigned to that service or procedures by CMS. These codes are known as the Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS codes are used by health care providers to represent what services have been provided and for which they are seeking reimbursement.

B. The Federal and State False Claims Acts

- 64. The Federal FCA creates liability for "any person who," among other things:
 - a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).
 - b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).
 - c. "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

- d. "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).
- 65. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. \$3729(a)(1). For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of \$5,500 to a maximum of \$11,000. See 28 C.F.R. \$85.3; 64 Fed. Reg. 47099, *47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of \$11,181 to a maximum of \$22,363. 28 C.F.R. \$85.5.
- 66. The FCA provides that "the terms 'knowing' and 'knowingly' (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).
- 67. The FCA provides that "the term 'claim' (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or

property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

- 68. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). Moreover, in the health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment...is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of...60 days after the date on which the overpayment was identified...or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act, March 23, 2010 ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), codified at 42 U.S.C. § 1128J9(d). See also 42 U.S.C. § 1320a-7k(d).
- 69. The FCA provides that "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).
- 70. Additionally, many states have passed False Claims Act laws, which in most instances closely track the Federal FCA. The State FCAs apply, *inter alia*, to the state portion of Medicaid losses caused by false or fraudulent Medicaid claims to the jointly federal-state funded Medicaid program and failure to report and return any overpayments therefrom. The Defendants'

acts alleged herein also constitute violations of the California False Claims Act, Cal. Govt. Code § 12650, et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. 25.5-4-303.5, et seq.; the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, et seg.; the Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201, et seq.; the Florida False Claims Act, Fla. Stat. § 68.081, et seq.; the Georgia Medicaid False Claims Act, Ga. Code. Ann. § 49-4-168, et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, et seq.; the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1, et seq.; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7, et seq.; the Iowa False Claims Act, Iowa Code § 685.1, et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1, et seq.; the Maryland False Health Claims Act, Md. Code Ann. Health-Gen § 2-601, et seq.; the Massachusetts False Claims Act, Mass. Ann. Laws Ch. 12 § 5A, et seq.; the Michigan Medicaid False Claims Act, Stat. Mich. Comp. Laws Serv. § 400.601, et seq.; the Minnesota False Claims Act, Minn. Stat. § 15C.01, et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401, et seg.; the Nevada Submission of False Claims to State and Local Government Act, Nev. Rev. Stat. § 357.010, et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1, et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1, et seq.; the New York False Claims Act, N.Y Fin. Law § 187, et seq.; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. § 63-5053, et seq. (2007); the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act, P.R. Laws Ann. tit. 32, § 2934, et seq. (2018); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code § 36.001, et seq.; the State of Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, et seq.; the Virginia

Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1, et seq.; the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.005, et seq.; the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. Ann. § 20.931, et seq. (repealed non-retroactively effective July 14, 2015); and the District of Columbia False Claims Act, D.C. Code Ann. § 2-381.01, et seq. Each of the statutes listed above contains qui tam provisions governing, inter alia, a relator's right to claim a share of the State's recovery.

C. The Anti-Kickback Laws of the United States and States

- 71. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute" or "AKS"), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1972 and has been amended many times since. The Anti-Kickback Statute arose out of Congressional concern that payoffs to those who can influence health care decisions corrupts medical decision-making and can result in goods and services being provided that are medically inappropriate, unduly costly, medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of Government Health Care Programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.
- 72. The Anti-Kickback Statute prohibits any person or entity from making or accepting "any remuneration" to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute's prohibition applies to both sides of an impermissible kickback relationship (i.e., the giver and the recipient of the kickback). The statute provides, in pertinent part:
 - (b) Illegal remunerations**

- (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
- a. To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
- b. To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

- 73. Underscoring the breadth of the statutory definition of remuneration, the Department of Health and Human Services, Office of Inspector General (HHS-OIG) Anti-Kickback Provisions, broadly define the term "remuneration" as "anything of value in any form whatsoever." 56 Fed. Reg. 35952, 35958 (1991).
- 74. Compliance with the federal and state anti-kickback laws is a precondition to participation and to payment as a health care provider under Medicare and Medicaid. *See generally United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011) (Medicare); *State of New York v. Amgen Inc.*, 652 F.3d 103 (1st Cir. 2011) (Medicaid). Violations of the AKS subject the perpetrator to liability under the federal FCA and no actual knowledge of the section or specific intent to commit a violation of the section is required. 42 U.S.C. §1320a-7b (g), (h). Accordingly, claims for payment for services that result from kickbacks are false or fraudulent under the FCA.
- 75. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. § 1320a-7(b)(7), 1320a-7a(a)(7).

- AKS, which apply to medical providers and entities participating in their Medicaid programs, including, without limitation, the States of California, Cal. Welf. & Inst. Code § 14107.2; Delaware, Del. Code. Ann. Tit. 31, § 1005; Florida, Fla. Stat. § 409.920(2)(a)(5); Illinois, 305 Ill. Comp. Stat. 5/8A; Louisiana, La. Rev. Stat. Ann. § 46:438.2; Massachusetts, Mass. Gen. Laws ch. 118E, § 41; Michigan, Mich. Comp. Laws § 400.604; New York, N.Y. Soc. Serv. Law § 366-d; and Virginia, Va. Code Ann. § 32.1-315. Pursuant to provider agreements and claim forms, providers who participate in a federal health care program including Medicare Part B generally must certify that they have complied with all applicable federal and State rules and regulations, including applicable anti-kickback statutes. *See* discussion *supra* at ¶ 61-63.
- 77. The Anti-Kickback Statute contains safe harbors that exempt certain transactions from its prohibitions. *See* 42 U.S.C. § 1320a-7(b)(3). Once the Government has demonstrated each element of a violation of the Anti-Kickback Statute, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by such a safe harbor or exception. The Government need not prove as part of its affirmative case that defendant's conduct at issue does not fit within a safe harbor.
- 78. As explained below, none of the safe harbors that would potentially apply to the kickbacks in this case exempt the relevant transactions.

V. <u>FACTS AND ALLEGATIONS</u>

A. Summary of Defendants' Unlawful Conduct

79. Cardinal engaged in a suite of related tactics to incentivize providers to switch to Cardinal and to switch from generic to branded drug products which cost the government and the patients more but are far more lucrative for Cardinal.

- 80. Cardinal Health offered illegal kickbacks in the form of prebates and signing bonuses, well in advance of drug purchases, to induce providers to enter exclusive distribution deals with it.
- 81. Further, these bribes fraudulently inflated the ASP of the drug, increasing the profit to providers who were reimbursed at 106% of the inflated ASP and causing the government to pay more for the drug to all providers.
- 82. VitalSource GPO served the interests of pharmaceutical drug manufacturers and helped them financially incent providers to switch their patients from low-cost generics to high cost branded drugs.
- 83. SPD utilized VitalSource GPO to funnel free goods and services to providers in order to induce them to enter into exclusive distribution contracts with SPD.
- 84. VitalSource GPO received of millions of dollars to use its position of trust with providers to assist pharmaceutical drug manufacturers to market drugs directly to them.
- 85. Through these schemes, which are detailed further below, the Cardinal Health Defendants have paid millions of dollars in illegal kickbacks to providers and induced billions of dollars in claims by the Medical Practice Defendants as a result; the Pharmaceutical Manufacturer Defendants have paid tens of millions of dollars in kickbacks to VitalSource and induced billions of dollars in claims; and the Medical Practice Defendants have submitted billions of dollars in false or fraudulent claims to Government Health Care Programs.

B. The Specialty Pharmaceutical Community Oncology Drug Market

86. "Specialty pharmaceuticals" are expensive biological drugs requiring special handling and prescribed for serious diseases including cancer. The products at issue here are developed and manufactured by pharmaceutical manufacturing companies. Manufacturers market specialty pharmaceuticals directly to providers.

- 87. Specialty pharmaceuticals are provided in several settings. At issue here is the community practice setting, *i.e.*, oncologist, hematologist, and urologist physician practices not part of hospitals. As explained below, these providers purchase drugs from distributors and bill insurers such as Government Health Care Programs for the administration of the drugs. The market is heavily weighted towards government payers, with Medicare Part B representing half of the relevant market.
- 88. When a community provider purchases drugs, it does so through a distributor such as Defendant SPD. The distributor makes wholesale purchases of drugs from the manufacturer and pays a negotiated price based on the Wholesale Acquisition Cost (WAC).

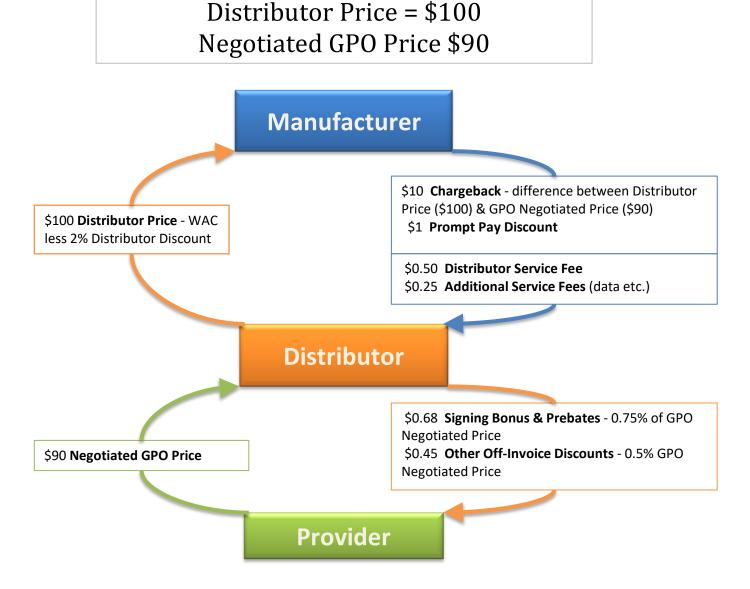
 WAC is a wholesale or benchmark price for the drug. For example, SPD would commonly pay WAC minus 1-2% for drugs.
- 89. The distributor then sells the drugs to a provider for substantially less than WAC at a price negotiated by the provider's Group Purchasing Organization (GPO). GPOs are buying consortiums or associations of healthcare providers designed to aggregate the purchasing power of members to drive down drug acquisition costs. GPOs negotiate pricing with manufacturers, but do not purchase any drug product themselves. Once a contract is in place, the member providers can make purchases at the contracted prices. GPOs are paid an Administrative Service Fees (ASF) by the manufacturer that must be 3% or less of purchases to stay within the AKS safe harbor for GPO fees. Department of Health and Human Services Office of Inspector General ("OIG") Report: "Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members," (A-05-03-00074) (Jan. 19, 2005).
- 90. Unique to the specialty pharmaceutical market, GPOs are not independent or controlled by their members, but instead captive entities wholly-owned and controlled by the

distributor, and membership in a particular GPO locks a provider into exclusive use of the affiliated specialty distributor. For example, VitalSource set pricing solely for drugs distributed by SPD. Likewise, a provider contracting with VitalSource was locked into purchasing from SPD.

- 91. Cardinal was well-aware of the symbiotic relationship between VitalSource and SPD and touted its success. For example, a 2015 internal GPO Business Review Presentation indicated that the GPO revenue growth was "primarily driven by. . . increased SPD volume." VitalSource providers were also aware of this relationship. When VitalSource would report to its members the Administrative Service Fees it received from manufacturers, providers would regularly call SPD executives and insist that SPD offer additional off-invoice discounts. These demands were frequently met. Cardinal Health pushed this symbiosis further than its competitors Amerisource and McKesson. Both competitors maintained separate GPO and distribution sales forces for compliance reasons. Cardinal sales representatives, however, "wore both hats" at the same time, eroding any practical separation between the entities and enabling sales force to offer price discounts beyond those negotiated with manufacturers.
- 92. Subsequent to the provider's purchase of drugs, the manufacturer makes several payments back to the distributor. First, the manufacturer pays the difference between the distributor price and the negotiated GPO price; this is called a chargeback. Then the manufacturer pays an approximate 1% discount for prompt payment by the distributor. Finally, the manufacturer pays a distributor fee of approximately .5% and additional service fees of about .25%.
- 93. Likewise, the distributor makes additional payments to the provider determined by the contract between them. In general, these discounts take the form of an across-the-board

discount to or rebate of the purchase price of every drug supplied by the distributor. Providers that do more overall volume generally receive better distributor discounts. SPD gave providers Signing Bonuses, prebates, and other "off-invoice discounts" that equated to approximately 1.25% of the negotiated GPO price paid by the provider.

94. This flow of payments is illustrated in the following figure:



- 95. Much of the complexity of the back and forth payments is explained by the manufacturer's attempts to comply with and the distributor's attempts to circumvent the calculation of the Average Sales Price (ASP).
- 96. Each quarter the manufacturer must report to the government the ASP of the drugs it sold. *See* 42 C.F.R. § 414.804. ASP is intended to reflect the actual price that providers pay for the purchase of the drugs. In calculating the ASP, the manufacturer must deduct "price concessions," including discounts, rebates, and chargebacks, but "*bona fide* service fees" are not considered a concession. *See* 42 C.F.R. § 414.804(a)(2) (emphasis added).
- 97. In the example above, the manufacturer would report an ASP of \$89 dollars reflecting the \$100 it was paid, less the \$10 chargeback and the \$1 prompt payment discount to the distributor. It would not deduct the distributor and additional service fees it pays to the distributor because *bona fide* fees are excluded from ASP, nor would it deduct the Signing Bonus, Prebates, or other off-invoice discounts the distributor pays to the provider as the manufacturer is presumably unaware of those payments.
- 98. When the manufacturer submits its quarterly ASP-required information to CMS, the manufacturer's CEO, CFO, or Authorizing Official must certify that "the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes." 42 C.F.R. § 414.805 and Form Addendum B.
- 99. When a provider administers a drug to a patient who is covered by a Government Health Care Program, it submits a claim to the program that includes the HCPCS code accurately representing the drug. Codes with a J prefix (known as J codes) represent the administration of a

drug covered under Medicare Part B. For example, J9070 represents the administration of 100 mg of cyclophosphamide, a common chemotherapy drug. Under Medicare Part B, CMS reimburses the provider 106% of the ASP. This reflects a judgment on the part of the government that the appropriate "profit" to the provider is 6% of the cost of the drugs. In the example above, the provider would receive a reimbursement of \$94.34.

- 100. However, insofar as a provider can lower its actual acquisition cost without unduly reducing the drug's ASP, it increases the profit that it realizes on each administration. There are two basic ways that Cardinal facilitated below-ASP prices to favored providers.
- arrangements with manufacturers that ensured the largest, favored practices paid well below average for the drugs. VitalSource divided its membership into three tiers. Non-Prime, Prime, and "Super Tankers." "Super Tankers" were a select group of about ten practices each generating annual revenues of over \$60 million. VitalSource would often negotiate tiered discounts, the best of which were available only to "Super Tankers" and ensured that the GPO-negotiated price that they paid was far below the ultimate ASP. For example, the Amgen XGEVA switching agreement discussed at ¶¶ 158-160, gave large practices the opportunity to reduce the price of the drug a further 6%, essentially doubling the Government's intended profit.
- 102. The second method for lowering acquisition costs without impacting reimbursement rates is to provide discounts to providers that are not reported to the government as part of its ASP calculation. Cardinal Health did that with its Signing Bonus, prebates, and offinvoice discounts.

¹ Other Government Health Care Programs operate similarly but utilize different methodologies for setting the price of the drug.

- 103. In the example above, the provider receives from the distributor an unreported \$1.13 in Signing Bonus, Prebates, and off-invoice discounts. "Super Tankers" that purchase upwards of \$500 million in goods annually, can realize an additional \$5,650,000 each year from these discounts. As explained, at Part V.C.6 *infra*, some of these discounts caused the manufacturers to falsely report the ASP and forced the government to overpay for all drugs.
- 104. Because the actual acquisition cost of the drug is opaque to the government and the services provided by the distributer are identical and fungible, there is a strong temptation to induce business from providers through the use of kickbacks, including in the form of unreported discounts, that increase the spread between the actual acquisition cost the provider pays and the ASP upon which government reimbursement is based.

C. The Prebate and Signing Bonus Kickback Schemes

1. The Genesis of the Scheme

- 105. Before 2012, Cardinal Health had no real presence in the community oncology specialty distribution market. At that time, the market was dominated by Cardinal Health competitors AmerisourceBergen and McKesson. Cardinal Health realized the enormous profits to be generated in this segment and moved aggressively to carve out a role for itself.
- 106. SPD faced a dilemma in trying to build a specialty pharmaceutical distribution business. Because its competitors sold the same products made by the same manufacturers and transported by the same means, providers correctly recognized that the services offered were essentially indistinguishable. Distributors generally compete on price, seeking to provide these drugs for the lowest costs. However, as a new market participant, SPD lacked the distribution volume and VitalSource GPO lacked the provider membership that would enable it to offer the same prices as its established competitors.

- 107. SPD recognized that the community specialty pharmaceutical market is unique in that providers purchase expensive specialty prescription drugs up front, administer the drugs, bill patients, and then wait at least 30 days to collect the reimbursement from an insurer. These upfront outlays run into the tens of millions of dollars each month for large oncology practices.
- 108. This structure means that the timing of payments plays an outsized importance in community oncology provider finances. SPD recognized this and made it an integral part of its highly successful strategy to capture market share. It did so by converting the ordinary rebate model (in which money follows the purchase of drugs) into two separate schemes in which Cardinal Health paid remuneration to practices months and years *before* purchases were made: the "Signing Bonus Scheme" and the "Prebate Scheme." As explained below, both of these schemes violate the AKS.
- 109. By structuring its inducements as upfront payments, SPD accomplished several goals.
- 110. First, the schemes were highly attractive to providers and Cardinal Health was able to leverage these payments into a massive capture of market share. Between 2012 and 2018, Cardinal Health used these agreements to increase its community oncology distribution volume from less than \$400 million to almost \$4 billion. Each contract signed by a provider committed it to purchasing 95% of its branded and generic pharmaceutical products from SPD.
- 111. Second, the clawback provisions made these agreements financially devastating for providers to terminate and had the effect of turning distribution contracts that permitted termination on ninety days written notice into effectively binding three-year commitments.

 While the clawback provisions were never actually enforced, they were used as a threat to deter defection by providers.

- 112. Finally, these payments perverted the fundamental incentive structure imposed by Government Health Care Providers by inducing providers to purchase and seek reimbursement for the most expensive drugs possible, even where lower cost generic drugs were equally beneficial and far more economical.
- arns modestly more when administering a more expensive drug, particularly where the provider can acquire the drug for less than the ASP. However, a physician must first purchase and pay for the drugs, administer them, and then await payment. This cash-flow issue provides a practical limit on the amount that a provider can outlay for drugs to enjoy a modestly higher profit. However, by offering physicians millions of dollars a year in upfront payments, Cardinal removes that limit from providers, aligning their interests in prescribing more expensive drugs.
- 114. This was of great value to Cardinal because not only are the GPO Administrative Service Fees and SPD distributor fees based on the cost of the drugs its providers purchase, but pharmaceutical manufacturers do not pay GPO Administrative Service Fees for generic drugs. Thus, Cardinal had a powerful incentive to move providers to more expensive drugs whenever possible and upfront payments facilitated this interest. This behavior had and has an orders-of-magnitude impact on Cardinal's revenue and profit as well as harm to Medicare and patients where they pay for a branded drug; for example, Medicare paid and still pays \$2,300 for XGEVA when the \$37 generic Pamidronate was and is available.

2. The Prebate Scheme

115. SPD Letters of Commitment (LOC) with providers contain a "Prebate Provision" described as an Annual Upfront Discount. It states that annually, SPD will pay the member a lump sum invoice credit based upon a negotiated percent of *estimated future purchases*.

116. For example, in October 2014, SPD signed a Letter of Commitment with Defendant Tennessee Oncology, a Nashville-based oncology practice with approximately \$500 million in annual purchases. That agreement contains a Prebate Provision that reads in part:

Annual Upfront Discount. No later than January 15 of each calendar year during the term of this LOC, Specialty Distribution shall pay to RainTree² Committed Member a 40 basis point discount on RainTree Committed Member's estimated future purchases of IV and injectable products from Specialty Distribution during the upcoming calendar year ("Annual Upfront Discount"). Estimated purchases for a calendar year will be equivalent to RainTree Committed Member's net purchases of all pharmaceutical products during the preceding calendar year. For the first calendar year, the Annual Upfront Discount dollar amount to be paid will be \$768,475.57. Such discount shall be paid in the form of a credit to Committed Member's account.

In June, 2016 the agreement was extended for another two years and the Prebate was increased to 43 basis points. The Prebate Provision contains a clawback/trueup provision that requires calculation of the actual purchases and repayment of any "unearned" prebates in the event the provider terminates the agreement before the three-year term ends or the earned rebates fall below the amount paid at the start of the year.

117. For example, the Tennessee Oncology Agreement clawback provision states in part:

If (i) this LOC is terminated for any reason prior to the end of the calendar year in which an Annual Upfront Discount was paid pursuant to this Section, or (ii) RainTree Committed Member's actual net purchases of all pharmaceutical products from Specialty Distribution multiplied by the applicable discount rate (the result of which is the "Actual Earned Discount") results in an Actual Earned Discount which is less than the Annual Upfront Discount payment for that calendar year, then RainTree Committed Member shall repay to Specialty Distribution the difference between (a) the actual Annual Upfront Discount amount paid to RainTree Committed Member for that calendar year and (b) the Actual Earned Discount for that same calendar year ("Repayment Amount").

² RainTree was a predecessor GPO that Cardinal Health acquired to jump-start VitalSource.

- 118. While the provision suggests that the Prebates were intended to accurately track earned rebates, in practice this provision was merely used as a threat to prevent contract termination or wholesale switching to cheaper drugs. The trueup amount was never calculated and no practice was ever asked to return prebates under it.
- 119. SPD entered into letters of commitment or extensions containing Prebate Provisions with many high-volume providers. These prebates totaled nearly \$26 million between 2014 and 2021, generating over \$1.237 billion in sales each year.

Provider	Dates	Annual Prebates Paid	Estimated Annual Purchase Volume	Estimated Annual Prebate	Estimated Total Prebate
Tennessee	2015-2019	43bps of previous	\$500,000,000	\$2,150,000	\$10,750,000
Oncology		12 months sales			
cCARE	2015-2019	40bps of previous 12 months sales	\$120,000,000	\$480,000	\$2,400,000
Alabama Oncology	2014-2019	35bps of previous 12 months sales	\$160,000,000	\$560,000	\$3,360,000
Tennessee Cancer	2015-2021	37bps of previous 12 months sales	\$170,000,000	\$629,000	\$4,403,000
Specialists					
South	2014-2019	30bps of previous	\$140,000,000	\$420,000	\$2,520,000
Carolina		12 months sales			
Oncology					
Ohio	2015-2020	30bps of previous	\$90,000,000	\$270,000	\$1,620,000
Oncology		12 months sales			
Cancer Care	2016-2019	30bps of previous	\$30,000,000	\$90,000	\$360,000
Northwest		12 months sales			
Pacific	2015-2019	25bps of previous	\$27,600,000	\$70,000	\$350,000
Cancer Center		12 months sales			
Health First	2015-2018	\$50,000		\$50,000	\$200,000
Medical					
Group					
Total	2014-2021		\$1,237,600,000	\$4,719,000	\$25,963,000

3. The Signing Bonus Scheme

- 120. SPD Letters of Commitment also contain a "Signing Bonus Provision" described as an Upfront Rebate. It states that within 30 days of the execution of the agreement, SPD will pay the member a lump sum "upfront discount" in the form of a check or credit memo on "future purchases to be made."
- 121. For example, in June 2016 (some twenty-one months after signing a thirty-six-month Letter of Commitment in October 2014), SPD and Tennessee Oncology amended their agreement to extend its term for an additional two years and to include the payment of a \$620,815 Signing Bonus:

<u>Upfront Discount</u>. Within the first thirty (30) days following the execution of this Amendment, Specialty Distribution shall pay to Committed Member an upfront discount in the amount of \$620,815 on future purchases to be made by the Committed Member during the term of this LOC ("Upfront Discount"). Such discount shall be paid in the form of a check or credit memo to Committed Member.

- 122. While the Signing Bonus purports to be a discount on future purchases, the contract does not provide any basis for calculating the Signing Bonuses. The dramatically different Signing Bonuses paid to various providers suggest that there was no principled basis for their determination, and they were simply the result of SPD's negotiation and the provider's insistence.
- 123. Similarly, while the provision indicates that the payment may be made by check or credit memo, the payments were invariably made by check within 30 days of the execution of the LOC consistent with the purpose of the payment as a bribe to induce a provider to sign or extend the Letter of Commitment.

- 124. Unlike the Prebate Provisions, the Signing Bonus Provisions contain no trueup provision that would modify the "discount" based on the actual amount of purchases. This is unsurprising given the lack of any objective basis for determining the Signing Bonus Amount.
- 125. Similarly, the Signing Bonus clawback provision is not based on a reconciliation of actual sales, as it is in the Prebate Provision. Instead, it is based on amortizing the Signing Bonus over the life of the LOC. For example, the Tennessee Oncology Amendment clawback provision states in relevant part:

If this LOC is terminated for any reason prior to the end of the term of this LOC, Committed Member shall repay to Specialty Distribution the unearned portion of the Upfront Discount. The unearned portion shall be determined by multiplying the Upfront Discount amount by a fraction, the numerator of which shall be the number of months remaining until the end of the term of this LOC at the time of termination and the denominator of which shall be the total number of months remaining in the Term of the LOC (as extended pursuant to this Amendment) as of the effective date of this Amendment ("Repayment Amount")

- 126. This too indicates that the Signing Bonus is falsely described as a "discount" when it is in fact simply an inducement to enter into the binding contract. Indeed, the Signing Bonus contains no requirement that the practice purchase anything.
- 127. SPD entered into LOCs and extensions containing Signing Bonus Provisions with many high-volume providers. These Signing Bonuses totaled over \$7.5 million, generating over \$1.7 billion in annual sales between 2015 and 2022.

Customer	LOC Period	Signing Bonus	Annual Purchase
Tennessee Oncology	2016-2019	\$620,815	\$500,000,000,
cCARE	2016-2019	\$203,206	\$120,000,000
Alabama Oncology	2016-2019	\$150,881	\$160,000,000
Clearview Cancer	2015-2019	\$1,500,000	\$200,000,000
Tennessee Cancer Specialists	2016-2021	\$285,302	\$170,000,000
South Carolina Oncology	2016-2019	\$149,810	\$140,000,000

Dayton Physicians	2017-2019	\$926,543	\$100,000,000
Michigan Healthcare	2017-2022	\$2,340,000	\$125,000,000
Ohio Oncology	2016-2020	\$92,930	\$90,000,000
Northwest Medical	2017-2020	\$1,200,000	\$100,000,000
Total	2015-2022	\$7,469,487	\$ 1,705,000,000

4. Upfront Payments Such as Prebates and Signing Bonuses Violate the AKS and Are Not Protected by Any Safe Harbor

- 128. The upfront payments that Cardinal Health paid to providers constitute remuneration under the AKS, which includes cash payments and discounts. *See* 42 U.S.C. § 1320a-7b(b). HHS-OIG has made this clear in regulatory guidance that "examples of remuneration in connection with a sale include, but are not limited to, 'prebates' and 'upfront payments,' other free or reduced-price goods or services, and payments to cover the costs of 'converting' from a competitor's product." HHS-OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg., 23731, 23736 (May 05, 2003) ("HHS-OIG Compliance Program Guidance").
- 129. Cardinal Health's signing bonuses and prebates were intended to induce providers to change their purchasing behavior and purchase drugs from Cardinal rather than its competitors. Moreover, Defendants knew these drugs were reimbursable under Medicare as the program covers over half the specialty drug prescriptions in this market. *See* 42 U.S.C. § 1320a-7b(b).
- 130. No AKS safe harbor permits the SPD's prebates and signing bonuses. In particular, the "Discount Safe Harbor" only protects discounts that are "made at the time of the sale," or rebates whose terms are "fixed and disclosed in writing to the buyer at the time of the initial sale" 42 C.F.R. § 1001.952(h)(1)(iii)(A).
- 131. HHS-OIG has repeatedly emphasized that upfront payments, prebates, or signing bonuses, whether or not labeled a "discount" or a "rebate," do not meet the requirements of the

discount safe harbor. For example, in 2003 HHS-OIG explained that the discount "exception covers only reductions in the product's price" and only if the discount is "given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (i.e., a rebate)." HHS-OIG, Compliance Program Guidance, 68 Fed. Reg., at 23735. That document further categorizes "prebates' and 'upfront payments," not as "discounts" but as "other remuneration to purchasers" in connection with a sale that "potentially implicates the anti-kickback statute and should be carefully reviewed." *Id.* at 23736.

- harbor to upfront payments in response to a medical product seller's inquiry into whether "arrangements involving advance contractual payments, variously described as (i) 'up-front rebates', (ii) 'signing bonuses', and (iii) 'prebates', implicate the Medicare and Medicaid anti-kickback statute." HHS-OIG, "Up front Rebates," "Prebates" and "Signing Bonus" Payments", Opinion Letter (Jul. 17, 2000) https://oig.hhs.gov/fraud/docs/safeharborregulations/prebate.htm. The payments discussed in the Opinion Letter are indistinguishable from those paid by SPD. There, the seller agreed "to pay substantial up-front payments to the Purchasers upon execution of the contract and may provide for additional advance payments to be made at various times during the terms of the contracts. The contracts would not provide for any refund to the Seller upon failure of the Purchasers to satisfy any minimum purchase requirements and may establish an exclusive purchasing relationship between the parties." *Id.*
- 133. HHS-OIG explained that these payments did not fall within the discount safe harbor because "they are made *prior* to any purchase and are *not attributable to identifiable* purchases of items or services. Simply put, discounts are price reductions at the time of sale of goods, and rebates are discounts subsequent to the sale." Id. (emphasis added).

- 134. HHS-OIG further explained that prebates and signing bonuses "pose a significant risk of fraud and abuse" for two reasons. First, they are "difficult to trace to ensure proper disclosure" as required by the safe harbor. Second, they "have the practical effects of 'locking in' the purchasers for an extended period of time, increasing the potential for overutilization and interfering with a purchaser's normal cost/quality considerations in ordering specific goods or services." Id. (emphasis added).
- 135. Cardinal Health's prebates and signing bonuses plainly fall outside of the safe harbor and represent a significant risk of fraud and abuse as they were set months, if not years, in advance of any sales. The prebates were set and paid at the beginning of each year, up to twelve months in advance of the purchases for which they were ostensibly discounting. Likewise, the signing bonus was set and paid at the signing of an exclusivity contract years before all of the purchases that the Bonus ostensibly discounted.
- 136. These agreements had the practical effect, as HHS-OIG feared, of locking Medical Practice Defendants into multi-year exclusive purchasing relationships with Cardinal Health.

5. Cardinal Health Knew These Payments Were Illegal

137. In 2008, Cardinal settled *United States ex rel. Saleaumua v. Cardinal Health, Inc*, a False Claims Act case involving nearly identical behavior to that described here. The United States alleged that Cardinal Health bribed the owners of a chain of community pharmacies with a \$440,000 signing bonus to expand market share over its competitor, McKesson, and thereby "weaken[ed] Medicare and Medicaid by steering taxpayer dollars into provider pockets, rather than into sound patient care." Press Release, DOJ, Ohio-Based Cardinal Health Inc. to Pay U.S. \$8 Million to Resolve False Claims Act Allegations (Apr. 21, 2011). In settling the matter, Cardinal was plainly aware that such payments are illegal kickbacks under the AKS and FCA.

- 138. Cardinal Health Specialty Solutions executives were aware of *Saleaumua*. The case was addressed at several compliance meetings during the pendency of SPD's signing bonus and prebate schemes.
- 139. Cardinal's prebates and signing bonuses were a powerful economic differentiator.

 Competitors AmerisourceBergen and McKesson were not offering them and quickly began to lose market share to Cardinal
- 140. Amerisource initially fought back against Cardinal's strategy by telling providers that Cardinal's signing bonuses and prebates were illegal. This information made its way back to Cardinal Health executives providing yet another basis for their knowledge that the scheme was improper.
- 141. However, after losing several large practices to Cardinal, including, notably Defendants Tennessee Oncology, cCARE, and Tennessee Cancer Specialists, Amerisource began to offer competing prebates and signing bonuses. Since Amerisource's about-face, "Super Tankers" Tennessee Oncology, South Carolina Oncology, and cCARE have ceased to do business with Cardinal and now contract with Amerisource.

6. These Payments Were Hidden From ASP Calculation

- 142. Cardinal Health has undermined the true ASP reported by drug manufacturers to Medicare (and other prices relative to other Government Health Care Programs) and increased the profit to providers.
- 143. Insofar as a provider can lower its actual acquisition cost below the drug's ASP, it increases the profit that it realizes on each administration. In the example, supra, ¶¶ 94-99, the provider effectively pays \$90 less the unreported \$1.13 in Signing Bonus, Prebates, and offinivoice discounts that it receives from the distributor, or \$88.87 \$.13 less than ASP. While an additional .13% discount on a drug with a WAC of \$100 may seem small, large providers

purchase upwards of \$500 million in goods annually, so that small difference translates to an additional \$650,000 each year.

- 144. As set forth above, since July 1, 2005, Medicare has based reimbursement for most Part B drugs on ASP, reported quarterly by the manufacturer to CMS. Manufacturers must deduct all "price concessions" from the calculation of ASP. 42 C.F.R. § 414.804(a)(3). Failure to do so inflates the ASP and results in Medicare overpaying for the drug.
- 145. "Price concession" *excludes* "bona fide service fees," such as the fees paid to distributors, *provided* that they represent fair market value for an itemized service actually performed on behalf of the manufacturer, *and that are not passed on*, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug. 42 C.F.R. § 414.802.
- 146. Thus, because they were structured as "service fees," the pharmaceutical manufacturers would not deduct SPD's distributor service fee and additional service fees from the ASP calculation. However, these fees do not in fact meet the requirements for *bona fide* service fees because they were passed on in part to SPD's clients as signing bonuses, prebates, and other illegal off-invoice discounts.
- 147. Cardinal Health fraudulently described the fees as *bona fide* service fees, when in fact they included money used to pay illegal kickbacks. As a result, manufacturers falsely reported a higher ASP to Medicare, compounding the value of the kickback to the provider by causing an artificially large reimbursement by Government Health Care Programs.
 - D. VitalSource GPO Was Used to Funnel Valuable Free SPD-provided Services to Physicians in Violation of the Anti-Kickback Statute
- 148. The AKS prohibits knowingly and willfully offering or paying remuneration directly or indirectly to induce a person to purchase goods paid for by a Government Health Care

- Program. 42 U.S.C. § 1320a-7b(b)(2)(B). "Examples of remuneration in connection with a sale include, but are not limited to, . . . free or reduced-price goods or services." HHS-OIG, Compliance Program Guidance, 68 Fed. Reg., at 23736.
- 149. Cardinal Health uses VitalSource GPO to funnel free SPD-funded (and other) services to GPO members to induce them to enter into exclusive distribution contracts with SPD thereby increasing the service fees SPD receives from manufacturers. In some cases, these services ostensibly carried fees, but Cardinal Health regularly waived these fees or offered offsetting billing credits to the practices for the services.
- 150. Cardinal Health provided the following valuable services that, in the absence of Cardinal's offers, would have to be purchased by the providers themselves. Beyond the economic incentives that Cardinal offered, these services provided a major point of differentiation on which practices chose to contract with Cardinal Health.
 - a. USP 800 educational resources devoted to helping providers obtain "knowledge of handling, preparing, administering and disposing of hazardous materials in preparation for the upcoming USP 800 standard." These expensive resources are necessary for oncology practices to open and operate a pharmacy.
 - b. **Practice Consultants** highly compensated experts holding advanced degrees (PharmD and MBA) who are provided to practices free of charge to help providers set up and operate their own pharmacies. Without this service, providers would have to locate and hire their own consultants. These experts provide free "Consultative Services," "Pharmacy Operations," and

- "Formulary Analyzer Consultative Services" that help providers increase profit.
- c. Site of Care Dispensing Program End-to-End Solution regulatory, legal, and management services necessary to opening and operating a pharmacy on site at the provider's office. These services include "research[ing] state regulations," "evaluat[ing] financial feasibility," "establish[ing] practice's NCPDP/NABP number," "perform[ing] necessary credentialing with payers," and "training staff."
- d. GPO Account Management Team full time consultants who help
 providers ensure patients are being treated in a manner to maximize discounts
 and rebates.
- e. FUSE by Cardinal Health Cardinal spent millions of dollars per year on a software development subsidiary called FUSE, which has over 100 employees. FUSE develops, installs, maintains, and updates software and hardware that is given free of charge to providers. These services, software, and hardware save providers millions of dollars in operating expenses. In fact, it would be virtually impossible for providers to replicate these capabilities on their own. FUSE's software "integrate[s] data analytics with 70+ EMRs and pharmacy systems . . . Drive[s] insights with cognitive and AI capabilities for payers, providers and manufacturers . . . and Captures data metrics to inform care options, improve workflow and decrease inefficiencies and cost." FUSE products given to practices include, among others, the following:

- i. Practice Analytics Core and Advanced Data analytics that ensure that the practice treats patients using drugs that maximize market share and aggregates rebates and discounts. Includes "GPO Contract Performance Dashboard," additional complex software to make sure the practice is treating patients in a way that maximizes rebates and discounts. The FUSE budget for these products was nearly \$1.5 million annually.Regimen Analyzer a web-based financial analysis tool that helps practices understand the financial implications of treatment decisions.
- ostensibly offered by VitalSource GPO, are in fact "owned" by SPD. For example, a 2015 VitalSource Business Overview presentation described the "Practice Analytics CORE offering" as "Core analytics provided to GPO members as part of SPD/GPO customer business". The presentation also explains that "Specialty Online," a web-based ordering product, and "VitalPath Inventory Management Solutions" are free services "owned by SPD."
- 152. Part of the intent behind these free and reduced-cost services is to induce providers to purchase drugs from SPD. As such, they are straightforward kickbacks in violation of the Anti-Kickback Statute. Cardinal used the services and value provided by VitalSource membership to increase the profit to SPD. For example, in 2016, VitalSource GPO designed a presentation to exhort its members to "Move as One" and act in concerted effort to obtain concessions from manufacturers. However, the concessions sought in at least some cases were for the exclusive benefit of SPD, and posed potential harms to VitalSource's members.

- chosen to distribute drugs outside of SPD. VitalSource requested that its members "reinforce[] the membership's position" and "[r]eward manufacturer partners who support our culture and our Community Oncology." In this case "support our culture and Community Oncology" meant increase the profits to SPD.Novartis was criticized for "elect[ing] to implement exclusive channel strategy," and forcing GPO membership "to order Novartis products through drop-ship from non-preferred distributor." The ultimate message to members was that "Novartis is making the job of community oncology more difficult solely to increase profitability." However, the request was driven not by VitalSource's concern for its members, but by its own interest in increasing the profit to its corporate sibling SPD which stood to lose out on lucrative distributor fees under Novartis's strategy.
- 154. VitalSource GPO members followed Cardinal's request and limited the access they granted Novartis's sales representatives. Novartis eventually caved and permitted SPD to distribute their drugs.
- 155. Likewise, Pharmacyclics was criticized for forcing "VitalSource GPO membership . . . to order Imbruvica through a non-preferred distributor." Again, the message to GPO membership was that "Pharmacyclics is making the job of community oncology more difficult solely to increase profitability." And again, the request was driven not by VitalSource's concern for its members, but by its own interest in increasing the profit to its corporate sibling SPD who stood to lose out on lucrative distributor fees under Pharmacyclics's strategy. VitalSource GPO members followed Cardinal's request and limited the access they granted Pharmacyclics's sales representatives. Pharmacyclics eventually caved and permitted SPD to distribute Imbruvica.

- date on new studies and treatments in the field as well as (ii) communicate their questions or concerns about products directly to the manufacturer. Providers who limited their access to manufacturers at VitalSource's request lost out on these benefits, both to the detriment of the providers' interests as well as their patients' safety. In requesting providers make sacrifices for SPD's profit, VitalSource operated as an extension of SPD, rather than a GPO on behalf of its members.
 - E. VitalSource GPO, Its Member Providers, and Manufacturers Act in Concert to Grow Certain Manufacturers' "Market Share" by "Switching" to Those Manufacturers' More Expensive Branded Drugs
- ability to leverage the GPO relationship on behalf of pharmaceutical manufacturers to encourage or cause the GPO members to switch some or all of their prescribing from one drug, typically a cheaper generic drug, to that manufacturer's drug. This is done in part through the use of so-called product share (*i.e.* "switching") contracts between VitalSource and the manufacturer through which the GPO member can access certain pricing which offers purported manufacturer "discounts" and/or "rebates" as higher levels of product share are achieved. In other words; the provider uses more of the contracted manufacturer's product and less of the (often cheaper) competing products. Under these contracts, the GPO member receives higher rebates/better pricing from the manufacturer the higher the market share achieved.
- 158. For example, Amgen and VitalSource engaged in a successful campaign to switch GPO members to Amgen's XGEVA from competitor drugs including generic Pamidronate.

 They did so by entering into a GPO agreement for the "product" XGEVA. The agreement prohibited VitalSource from "counter-detailing," *i.e.* directly encouraging a GPO customer to switch its order to a product that competes with XGEVA, except in certain limited situations, and

provided multiple types of discounts to providers. Four of the five discounts were not determined using the volume of XGEVA purchased and used. Rather, they were based on the market or product share of the GPO member's purchases of XGEVA versus "competitive products" including Pamidronate, Zometa and pamidronic acid plus any new drug that might receive FDA approval during the contract period. These discounts included:

- a. a "Product Share Invoice Discount" of 1% for product share less than 30%,
 1.0% for product share over 30% but less than 45%, 2% for product share over 45% but less than 60%, and 3% for product share greater than 60%;
- a Loyalty Discount of 2.0% if the XGEVA product share exceeds 30% (and 0% for anything below that);
- c. a "Large Practice XGEVA Invoice Discount" which generally speaking was calculated based on LP Aggregate XGEVA Product Share, i.e., the volume of XGEVA purchased divided by the total volume of XGEVA and competitive products purchased; if the LP Aggregate Product Share was 38% or higher, the practice was eligible to receive a further discount of 1.0 % (recently amended to increase the discount from 1% to 6% maximum, depending on market share achieved).
- d. a Base Invoice Discount of 2% applied to the WAC of the drug for a member who became a new purchaser of XGEVA (i.e. had no purchases of XGEVA prior to the effective date of their joining the GPO); and
- e. a 1.0 % Volume Invoice Discount if a provider's purchases of XGEVA exceeded a certain number of units during the period.

- 159. Of these five types of discounts, only the Volume Invoice Discount was actually based on sales volume. The other discounts were based either on (a) the ratio of XGEVA used compared to competitor products by the GPO member/physician practice (your volume could actually go down because of fewer patients, for example, but you could still receive the discount); or (b) if you were a new XGEVA user (regardless of how much you purchased). When combined, they permitted large practices to reduce the cost of XGEVA a further 6% or essentially doubling the government's intended profit to the physician.
- 160. In all cases, under the agreement, the only authorized wholesaler from whom XGEVA could be distributed to the provider was Cardinal.
- 161. This arrangement had a dramatic effect on the prescribing habits of VitalSource members. In 2014, XGEVA enjoyed a market share of between 41% and 45% among VitalSource providers enrolled in the program. However, by the fourth quarter of 2016, XGEVA had achieved a nearly 100% market share (99.97% to be precise).
- Velcade) and Eli Lilly and Company (for the drug Alimta), the GPO agreements between VitalSource and the manufacturer provide so-called "growth" discounts if a group of practices can grow their aggregate use of the relevant drug by a certain amount. Such "growth discounts" are in fact disguised market share discounts given that there is a finite cohort of cancer patients in any given area.
- 163. Moving aggregate market share could also result in VitalSource receiving a higher ASF from a manufacturer. For example, at one point in time, Amgen increased the ASF on Aranesp and Neulasta from 1% to 2% (which equated to an additional \$1 million per year for

VitalSource) as a reward for the aggregate market share of its drugs exceeding 10% across the GPO's membership.

- 164. In 2003, the HHS-OIG Compliance Program Guidance noted that: "Product conversion arrangements (also known as 'switching arrangements') are suspect under the anti-kickback statute. Switching arrangements involve pharmaceutical manufacturers offering physicians or others cash payment or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product. This activity clearly implicates the statute...." *Id.*, 68 Fed. Reg., at 23738. "Payments to pharmacies for switching patients from one drug to another, and for other efforts to increase a drug's utilization do not qualify as protected price reductions simply because the payments are labeled as 'rebates' or 'discounts'." Statement of Interest on Behalf of the United States of America in Response to Defendants' Motion to Dismiss the Complaint ("*Organon* Statement of Interest") at 5, *United States ex rel.*
- 165. Thus, "payments by drug manufacturers" to customers "in return for efforts to switch patients to the manufacturers' drugs and increase utilization are not 'discounts,' and therefore do not implicate either the discount exception in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(3)(A), or the discount regulatory safe harbor, 42 C.F.R. § 1001.952(h)." See Organon Statement of Interest at 2; see also Memorandum Decision and Order, United States ex rel. Kester v. Novartis Pharms. Corp., No. 11 Civ. 8196 CM (S.D.N.Y. Jan. 6, 2015); United States ex rel. Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242 (S.D.N.Y. 2014); United States ex rel. Banigan & Templin v. Organon USA Inc., 883 F. Supp. 2d 277, 295-296 (D. Mass. 2012).

F. VitalSource GPO Solicits and Accepts Payments From Manufacturers For Assisting With Marketing to GPO Members

- 166. VitalSource successfully solicited and received millions of dollars in payments from the Pharmaceutical Manufacturer Defendants to arrange meetings, called "Strategic Planning Meetings," between the manufacturers and high-volume GPO members. These kinds of meetings were, to Relators' knowledge, not offered by VitalSource's counterparts at AmerisourceBergen or McKesson.
- approximately \$78,000, nearly \$20,000 per one-hour session, and explained the value to manufacturers in explicit marketing terms. Manufacturers were told that the meeting would "Help pharma understand practice decision making, prescribing patterns and clinical experience" as well as "[f]oster manufacturer, practice and GPO relationship building," and contain an "interactive discussion to share information and discover collaborative opportunities." In reality, VitalSource and the manufacturers recognized these phrases to mean that pharmaceutical sales and marketing staff could directly lobby physicians to switch patients to their drugs, including by discussing the economic incentives.
- 168. Part of the marketing package involved "data pull and analysis." VitalSource obtained this information directly from the practice's electronic health records, pursuant to a clause in its contract with the provider. VitalSource then performed sophisticated data analytics on it producing a "market basket report for targeted drugs by prescriber and patient." This granular level prescribing data permitted the manufacturer to laser focus its marketing presentation.
- 169. Prior to these meetings, manufacturers were permitted to craft a survey regarding a practice's experiences. These surveys tended to focus on physicians' reasons for choosing

competitors' drugs. Practice physicians were paid approximately \$300/hour to complete the surveys. VitalSource would collate the survey results and provide them to the manufacturer. This would facilitate the in-meeting discussions which centered around how the manufacturer could convince the practice to switch to their products.

- 170. The meetings would typically be attended by the medical practice's CEO, Chief Medical Officer, and Director of Pharmacy. Manufacturers could (and generally did) insist that "Target MDs" attend as well. The pharmaceutical manufacturer would send high-ranking (Vice President-level or higher) executives from sales, medical, and marketing, and would expect commensurate results for the investment.
- 171. These meetings were sold to manufacturers on the basis of the sales and marketing opportunities. These discussions encompassed not only medical bases for choosing their drugs over a competitors' or a generic, but also the relative reimbursement rates and the extent to which choosing their drug would impact the physician's bottom-line.
- 172. As an expensive marketing opportunity, manufacturers were interested in purchasing Strategic Planning Meetings only with large volume providers. This created difficulty because all the manufacturers wanted to hold meetings with the same few providers, such as Tennessee Oncology and cCARE, because those practices would drive volume for them, but those providers did not want to spend all of their time in these meetings.
- 173. To induce the practices to attend these meetings, VitalSource offered them the same data it produced for manufacturers. It claimed the data would provide a better understanding of any differences between perceived treatment practices and actual treatment practices based on actual treatment data by physician in the practice. Moreover, it gave the practice a unique opportunity to discuss pricing issues directly with the manufacturer executive.

- 174. In total, VitalSource sold \$507,500 worth of Strategic Planning Meetings to pharmaceutical manufacturers in 2017 and 2018. For example, Defendant Bayer purchased meetings to market its drug Xofigo; Defendant Exelixis purchased meetings to market its drug, Cabometyx, and Defendant Takeda purchased meetings to market Ninlaro. In return for these purchases, VitalSource induced many high-volume providers to attend these meetings. For example, in 2017, Defendants South Carolina Oncology and Dayton Physicians each attended one Strategic Planning Meeting, and Tennessee Oncology attended two; Defendant South Carolina Oncology also made plans to attend one additional meeting. In 2018, Defendants Ohio Oncology, and Dayton Physicians each planned to attend one Strategic Planning Meeting.
- 175. VitalSource also sold a more traditional marketing opportunity it called InPractice Programming for \$16,500 per session. This was also described in explicitly sales-related terms. VitalSource explained that it provided manufacturers value by providing a "structured environment to deliver promotional product or disease state messaging to member practice."

 Meetings similar to these were also held by McKesson and AmerisourceBergen.
- 176. VitalSource sold In Practice Programming to many pharmaceutical manufacturers and induced many high-volume providers to attend. In total, VitalSource sold \$2,646,000 of these meetings in 2017 and 2018.

1. These programs violate the Anti-Kickback Statute

177. As explained above, the Anti-Kickback Statute makes it a criminal offense to offer, pay, solicit, or receive any remuneration in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good reimbursable under Government Health Care Programs. 42 U.S.C. § 1320a-7b(b). For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. *Id*.

- 178. Here VitalSource solicits "remuneration" from the Pharmaceutical Manufacturer Defendants to arrange or recommend the purchase of Government Health Care Program-paid drugs. Further, VitalSource provides "remuneration" in the form of expensive data analysis to physician practices to induce their attendance at these meetings where they are influenced to buy these drugs. By its terms, the statute imposes liability on both parties on both sides of the impermissible transactions.
- violate the AKS, noting in the preamble to the 1991 final safe harbor rules that "prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs." 56 Fed. Reg. 35952, 35952 (July 29, 1991). That same rulemaking explicitly concluded that "many marketing and advertising activities may involve at least technical violations of the statute." *Id.* HHS-OIG went on to explain that "many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, *i.e.*, the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals or entities are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients." *Id.*
- 180. Likewise, HHS-OIG has understood that the relationship between a pharmaceutical manufacturer and GPO is a "remunerative relationship[] with persons or entities in a position to refer, order, or prescribe *or influence the referral, ordering, or prescribing of* the manufacturer's products, even though the persons or entities may not themselves purchase

(or, *in the case of GPOs* or PBMs, arrange for the purchase of) those products." HHS-OIG Compliance Program Guidance, 68 Fed. Reg., at 23736. Thus, HHS-OIG has stated that these "remunerative relationships potentially implicate the anti-kickback statute." *Id*.

- 181. The AKS violation becomes more certain when, as with all such marketing and sales expenditure, one purpose of the remuneration is to induce the sale of goods.
- 182. HHS-OIG advises that "prudent manufacturers and their agents or representatives should structure relationships" with entities in a position to influence referrals "to fit in an available safe harbor" such as the personal services safe harbor. *Id.* Furthermore, the "arrangement must fit squarely in a safe harbor to be protected." *Id.*
- 183. Pharmaceutical manufacturers pay remuneration (nearly \$20,000) to VitalSource and one purpose for this payment is to influence the purchase of Medicare reimbursed drugs. VitalSource pays remuneration in the form of valuable data analysis to the providers to induce them to attend these meetings and be influenced.
- 184. No safe harbor protects the pharmaceutical manufacturer's payment of nearly \$20,000 or VitalSource's offer of valuable data analysis.
- 185. The Personal Services exception is the only safe harbor potentially applicable to this behavior, and does not apply on these facts. Even if these payments met all other requirements of the safe harbor, they are not "consistent with fair market value in arms-length transactions" and they are "determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties." 42 C.F.R. § 1001.952(d)(5).
- 186. The legitimate services obtained by the pharmaceutical manufacturer in exchange for the payment of \$20,000 include the nominal value of setting up a meeting, administering and

collating physicians' surveys, and the proprietary data analytics performed on the provider data. Thus, in any fair market value analysis, most of the "value" of the purchase would have to be allocated to the data analysis. However, that same data and analysis were given free to the physicians and providers to induce them to attend the meeting. Thus, under any fair market value analysis, the manufacturer's payment of tens of thousands of dollars for the meeting would mean that the providers had been given an incredibly valuable service at no cost as an inducement to attend marketing sessions.

187. Cardinal Health determined the payments to providers in a manner that took into account the volume and value of referrals, because these meetings were offered primarily to the providers with the largest purchasing volume. This makes sense of course; as an expensive marketing opportunity, manufacturers could not justify the expense for marginal sales opportunities. But it also means that the valuable data analytics were given to providers on the basis of their purchasing volume, precluding application of the safe harbor.

G. Harm to the Government and Patients

- 188. The illegal arrangements described above were a "win, win," for the Cardinal, Medical Practice, and Pharmaceutical Manufacturer Defendants.
 - a. Between 2012 and 2018, Cardinal Health increased its community oncology distribution volume from less than \$400 million to almost \$4 billion.
 Cardinal's market share in the community oncology distribution business, relative to its competitors, went from less than 5% in 2012 to 20% at the end of 2018.
 - b. Medical Practices received lucrative upfront payments and other benefits that were not included in the Manufacturers' calculation of ASP, enabling the

- providers to be reimbursed at an inflated ASP and an increased profit margin on the drugs they purchased and administered.
- c. Pharmaceutical manufacturers who made and sold expensive branded specialty pharmaceuticals were able to grow the market share for their drugs over competitors' drugs and over much less expensive generic drugs.
- 189. Conversely, the Government was harmed by paying higher prices for drugs. So too patients were harmed through more expensive co-pays and deductibles. For example, Medicare reimburses Amgen's XGEVA at \$2,300, when \$37 generic Pamidronate was and is available.
- 190. Moreover, providers may have not only prescribed a more expensive drug, but ones that were less desirable for the patient's treatment; in one instance, a manufacturer noted that without the rebates, it would not have hit its growth and revenue targets on a cancer drug "particularly as a 12 year old product with a competitor having lower toxicity." In other words, a cancer patient received a more expensive drug with a higher toxicity rather than an established drug with a lower toxicity.

VI. <u>DAMAGES</u>

- 191. Through these schemes, the Cardinal Health Defendants have paid millions in illegal kickbacks to providers and induced billions in claims by the Medical Practice Defendants as a result. For example, \$7.5 million of (1) undisclosed/unreported signing bonuses paid by (2) Cardinal to oncologists (3) upon contract execution (4) years prior to any product purchases (5) to switch and/or lock in \$1.7 billion per year in purchases in (6) an exclusive purchasing arrangement.
- 192. In addition, the Pharmaceutical Manufacturer Defendants have paid millions in kickbacks to VitalSource and induced billions in claims.

VII. CLAIMS FOR RELIEF

Count I

Federal False Claims Act – False Claims 31 U.S.C. § 3729(a)(1)(A) (2009)

- 193. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.
- 194. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.
- 195. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval.
- 196. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.
- 197. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 198. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count II

Federal False Claims Act – False Records or Statements 31 U.S.C. § 3729(a)(1)(B) (2009)

- 199. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.
- 200. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.

- 201. By and through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.
- 202. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.
- 203. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 204. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count III

Federal False Claims Act – Reverse False Claims 31 U.S.C. § 3729(a)(1)(G) (2009)

- 205. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.
- 206. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.
- 207. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the Government and they have concealed and improperly avoided an obligation to pay money to the Government, including specifically Defendants' obligation to report and repay past overpayments of Medicare and other Government Health Care Program claims for which Defendants knew they were not entitled to and therefore refunds were properly due and owing to the United States.

- 208. The Government, unaware of the concealment by the Defendants, has not made demand for or collected the years of overpayments due from the Defendants.
- 209. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 210. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count IV

Federal False Claims Act - Conspiracy 31 U.S.C. § 3729(a)(1)(C) (2009)

- 211. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs above as though fully set forth herein.
- 212. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.
- 213. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that billions in payments from the federal government have been received in violation of the False Claims Act and in violation of the Anti-Kickback Statute's prohibition on receipt of payment for services rendered in connection with an improper financial arrangement, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.
- 214. The Government, unaware of the Defendants' conspiracy and fraudulent schemes, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

- 215. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 216. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 (or other statutory maximum provided for by law) for each and every violation alleged herein.

Count V

California False Claims Act Cal. Gov't Code § 12650, et seq.

- 217. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 218. This is a civil action brought by Relators, on behalf of the State of California, against Defendants under the California False Claims Act, Cal. Gov. Code § 12652(c).
- 219. The California FCA, Cal. Gov. Code § 12651(a)(1), creates liability for any person who "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the California FCA.
- 220. The California FCA, Cal. Gov. Code § 12651(a)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the California FCA.
- 221. The California FCA, Cal. Gov. Code § 12651(a)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an

obligation to pay or transmit money or property to the state or to any political subdivision."

Defendants have violated this provision of the California FCA.

- 222. The California FCA, Cal. Gov. Code § 12651(a)(3), creates liability for any person who "[c]onspires to commit a violation of this subdivision." Defendants have violated this provision of the California FCA.
- 223. Pursuant to the California FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Cal. Gov. Code § 12651(a)(1).

Count VI

Colorado Medicaid False Claims Act Colo. Rev. Stat. § 25.5-4-303.5, et seq.

- 224. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 225. This is a civil action brought by Relators, in the name of the State of Colorado, against Defendants pursuant to the State of Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306 et seq..
- 226. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(a), creates liability for any person who "[k]nowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Colorado FCA.
- 227. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Colorado FCA.

- 228. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(f), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the 'Colorado Medical Assistance Act', or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the 'Colorado Medical Assistance Act'." Defendants have violated this provision of the Colorado FCA.
- 229. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(g), creates liability for any person who "[c]onspires to commit a violation of paragraphs (a) to (f) of this subsection (1)" Defendants have violated this provision of the Colorado FCA.
- 230. Pursuant to the Colorado FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Colo. Rev. Stat. § 25.5-4- 305(1).

Count VII

Connecticut False Claims Act Conn. Gen. Stat. § 4-274, et seq.

- 231. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 232. This is a civil action brought by Relators, in the name of the State of Connecticut, against Defendants pursuant to the State of Connecticut False Claims Act, Conn. Gen. Stat. § 4-277.
- 233. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(1), provides that no person shall "[k]nowingly present, or cause to be presented, a false or fraudulent claim for payment or

approval under a state-administered health or human services program." Defendants have violated this provision of the Connecticut FCA.

- 234. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(2), provides that no person shall "[k]nowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program."

 Defendants have violated this provision of the Connecticut FCA.
- 235. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(7), provides that no person shall "[k]nowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program." Defendants have violated this provision of the Connecticut FCA.
- 236. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(8), provides that no person shall "[k]nowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program." Defendants have violated this provision of the Connecticut FCA.
- 237. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(3), provides that no person shall "[c]onspire to commit a violation of this section." Defendants have violated this provision of the Connecticut FCA.
- 238. Pursuant to the Connecticut FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Conn. Gen. Stat. § 4-275(b).

Count VIII

Delaware False Claims And Reporting Act Del. Code Ann. Tit. 6 §§ 1201, et seq.

- 239. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 240. This is a civil action brought by Relators, on behalf of the Government of the State of Delaware, against Defendants under the State of Delaware's False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1203(b)(1).
- 241. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(1), creates liability for any person who "[k]nowingly presents, or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Delaware FCA.
- 242. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(2), creates liability for any person who "[k]nowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Delaware FCA.
- 243. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Defendants have violated this provision of the Delaware FCA.
- 244. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(3), creates liability for any person who "[c]onspires to commit a violation of" the law. Defendants have violated this provision of the Delaware FCA

245. Pursuant to the Delaware FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Del. Code Ann. tit. 6, §1201(a).

Count IX

District of Columbia False Claims Act D.C. Code Ann. §§ 2.381.01, et seq.

- 246. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 247. This is a civil action brought by Relators, in the name of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code Ann. § 2-381.03(b)(1).
- 248. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(1), creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the D.C. FCA.
- 249. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the D.C. FCA.
- 250. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(6), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the District, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the District." Defendants have violated this provision of the D.C. FCA.

- 251. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(7), creates liability for any person who "[c]onspires to commit a violation of paragraph." Defendants have violated this provision of the D.C. FCA.
- 252. Pursuant to the D.C. FCA, Defendants are thus liable to the District for statutorily defined damages sustained because of the acts of Defendants and civil penalties. D.C. Code Ann. § 2-381.02(a).

Count X

Florida False Claims Act Fla. Stat. § 68.081, et seq.

- 253. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 254. This is a civil action brought by Relators, on behalf of the State of Florida, against Defendants under the State of Florida's False Claims Act, Fla. Stat. § 68.083(2).
- 255. The Florida FCA, Fla. Stat. § 68.082(2)(a), creates liability for any person who "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Florida FCA.
- 256. The Florida FCA, Fla. Stat. § 68.082(2)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Florida FCA.
- 257. The Florida FCA, Fla. Stat. § 68.082(2)(g), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendants have violated this provision of the Florida FCA.

- 258. The Florida FCA, Fla. Stat. § 68.082(2)(c), creates liability for any person who "[c]onspires to commit a violation of this subsection." Defendants have violated this provision of the Florida FCA.
- 259. Pursuant to the Florida FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Fla. Stat. § 68.082(2).

Count XI

Georgia False Medicaid Claims Act Ga. Code Ann. §§ 49-4-168, et seq.

- 260. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 261. This is a civil action brought by Relators, in the name of the State of Georgia, against Defendants pursuant to the State of Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).
- 262. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(1), creates liability for any person who "[k]nowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Georgia FCA.
- 263. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Georgia FCA.
- 264. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement

material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program." Defendants have violated this provision of the Georgia FCA.

- 265. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(3), creates liability for any person who "Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid." Defendants have violated this provision of the Georgia FCA.
- 266. Pursuant to the Georgia FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Ga. Code Ann. § 49-4-168.1(a).

Count XII

Hawaii False Claims Act Haw. Rev. Stat. §§ 661-21, et seq.

- 267. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 268. This is a civil action brought by Relators, on behalf of the State of Hawaii and its political subdivisions, against Defendants under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-25(a).
- 269. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(l), creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Hawaii FCA.
- 270. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Hawaii FCA.

- 271. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(6), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendants have violated this provision of the Hawaii FCA.
- 272. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(8), creates liability for any person who "Conspires to commit any of the conduct described in this subsection." Defendants have violated this provision of the Hawaii FCA.
- 273. Pursuant to the Hawaii FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Haw. Rev. Stat. § 661-21(a).

Count XIII

Illinois False Claims Act 740 Ill. Comp. Stat. §§ 175/1, et seq.

- 274. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 275. This is a civil action brought by Relators, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/4(b).
- 276. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(A), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Illinois FCA.
- 277. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(B), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement

material to a false or fraudulent claim." Defendants have violated this provision of the Illinois FCA.

- 278. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(G), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendants have violated this provision of the Illinois FCA.
- 279. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(C), creates liability for any person who "conspires to commit a violation of" the law. Defendants have violated this provision of the Illinois FCA.
- 280. Pursuant to the Illinois FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. 740 Ill. Comp. Stat. § 175/3(a).

Count XIV

Indiana Medicaid False Claims and Whistleblower Protection Act Ind. Code § 5-11-5.7, et seq.

- 281. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 282. This is a civil action brought by Relators, on behalf of the State of Indiana, against Defendants under the State of Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7-4(a).
- 283. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(l), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Indiana FCA.

- 284. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(2), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim." Defendants have violated this provision of the Indiana FCA.
- 285. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(6)(A)-(B), creates liability for any person who "(A) makes, uses, or causes to be made or used, a false record or statement concerning an obligation to pay or transmit money or property to the state; or (B) conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendants have violated this provision of the Indiana FCA.
- 286. The Indiana FCA, Ind. Code § 5-11-5.5-2(b)(7), creates liability for any person who "conspires with another person to perform an act described in subdivisions (1) through (6)." Defendants have violated this provision of the Indiana FCA.
- 287. Pursuant to the Indiana FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Ind. Code § 5-11-5.5-2(b).

Count XV

Iowa False Claims Act Iowa Code §§ 685.1, et seq.

- 288. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 289. This is a civil action brought by Relators, on behalf of the State of Iowa, against Defendants under the State of Iowa False Claims Act, Iowa Code § 685.3(2).a.

- 290. The Iowa FCA, Iowa Code § 685.2(1).a, creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Iowa FCA.
- 291. The Iowa FCA, Iowa Code § 685.2(1).b, creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Iowa FCA.
- 292. The Iowa FCA, Iowa Code § 685.2(1).g, creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendants have violated this provision of the Iowa FCA.
- 293. The Iowa FCA, Iowa Code § 685.2(1).g, creates liability for any person who "conspires to commit a violation of" the law. Defendants have violated this provision of the Iowa FCA.
- 294. Pursuant to the Iowa FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Iowa Code § 685.2(1).

Count XVI

La. Rev. Stat. Ann. §§ 46:437.1, et seq.

295. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.

- 296. This is a civil action brought by Relators, on behalf of the State of Louisiana's medical assistance programs, against Defendants under the State of Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.A.
- 297. The Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.A, provides that "[n]o person shall knowingly present or cause to be presented a false or fraudulent claim." Defendants have violated this provision of the Louisiana FCA.
- 298. The Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.B, provides that "[n]o person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Louisiana FCA.
- 299. The Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.C, provides that "[n]o person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs." Defendants have violated this provision of the Louisiana FCA.
- 300. The Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.D, provides that "[n]o person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim." Defendants have violated this provision of the Louisiana FCA
- 301. Pursuant to the Louisiana FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. La. Rev. Stat. Ann. § 46:438.6.

Count XVII

Maryland False Health Claims Act Md. Code Ann. Health-Gen. §§ 2-601, et seq.

- 302. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 303. This is a civil action brought by Relators, on behalf of the State of Maryland, against Defendants under the State of Maryland False Health Claims Act, Md. Code Ann. Health-Gen. § 2-604(a)(1).
- 304. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(1), provides that a person may not "[k]nowingly present or cause to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Maryland FCA.
- 305. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(2), provides that a person may not "[k]nowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Maryland FCA.
- 306. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(7), provides that a person may not "[k]nowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State." Defendants have violated this provision of the Maryland FCA.
- 307. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(8), provides that a person may not "[k]nowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State." Defendants have violated this provision of the Maryland FCA.

- 308. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(9), provides that a person may not "[k]nowingly make any other false or fraudulent claim against a State health plan or a State health program." Defendants have violated this provision of the Maryland FCA.
- 309. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(3), provides that a person may not "[c]onspire to commit a violation under this subtitle." Defendants have violated this provision of the Maryland FCA.
- 310. Pursuant to the Maryland FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Md. Code Ann. Health-Gen. § 2-602(b).

Count XVIII

Massachusetts False Claims Act Mass. Gen. Laws Ch. 12, § 5a, et seq.

- 311. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 312. This is a civil action brought by Relators, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Ann. Laws, ch. 12, § 5C(2).
- 313. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(1), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Massachusetts FCA.
- 314. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(2), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Massachusetts FCA.

- 315. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(9), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof." Defendants have violated this provision of the Massachusetts FCA.
- 316. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(3), creates liability for any person who "conspires to commit a violation of this subsection." Defendants have violated this provision of the Massachusetts FCA.
- 317. Pursuant to the Massachusetts FCA, Defendants are thus liable to the Commonwealth for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Mass. Ann. Laws, ch. 12, § 5B(a).

Count XIX

Michigan Medicaid False Claims Act Mich. Comp. Laws Serv. §§ 400.601, et seq.

- 318. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 319. This is a civil action brought by Relators, in the name of the State of Michigan, against Defendants under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).
 - 320. The Michigan FCA, Mich. Comp. Laws. Serv. § 400.603(1)-(3), provides that:
 - "(1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits.
 - (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit.

(3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled."

Defendants have violated each of these provisions of the Michigan FCA.

- 321. The Michigan FCA, Mich. Comp. Laws. Serv. § 400.607(1), provides that "[a] person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false." Defendants have violated this provision of the Michigan FCA.
- 322. The Michigan FCA, Mich. Comp. Laws. Serv. § 400.607(3), provides that "[a] person shall not knowingly make, use, or cause to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act." Defendants have violated this provision of the Michigan FCA.
- 323. The Michigan FCA, Mich. Comp. Laws. Serv. § 400.606(1), provides that "[a] person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim 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." Defendants have violated this provision of the Michigan FCA.
- 324. Pursuant to the Michigan FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Mich. Comp. Laws. Serv. § 400.612.

Count XX

Minnesota False Claims Act Minn. Stat. §§ 15c.01, et seq.

- 325. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 326. This is a civil action brought by Relators, on behalf of the State of Minnesota and its political subdivisions, against Defendants under the State of Minnesota False Claims Act, Minn. Stat. § 15C.05(a).
- 327. The Minnesota FCA, Minn. Stat. § 15C.02(a)(1) creates liability for any person who, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Minnesota FCA.
- 328. Minnesota FCA, Minn. Stat. § 15C.02(a)(2) creates liability for any person who "knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Minnesota FCA.
- 329. Minnesota FCA, Minn. Stat. § 15C.02(a)(7) creates liability for any person who "knowingly makes or uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision." Defendants have violated this provision of the Minnesota FCA.
- 330. Minnesota FCA, Minn. Stat. § 15C.02(a)(3) creates liability for any person who "knowingly conspires to commit a violation of" the law. Defendants have violated this provision of the Minnesota FCA.

331. Pursuant to the Minnesota FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties.

Minn. Stat. § 15C.02(a).

Count XXI

Montana False Claims Act Mont. Code Ann. §§ 17-8-401, et seq.

- 332. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 333. This is a civil action brought by Relators, on behalf of the State of Montana, against Defendants under the State of Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).
- 334. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(a), creates liability for any person who, "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Montana FCA.
- 335. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(b), creates liability for any person who "knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Montana FCA.
- 336. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(g), creates liability for any person who "knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to a governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity." Defendants have violated this provision of the Montana FCA.

- 337. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(c), creates liability for any person who "conspires to commit a violation of this subsection." Defendants have violated this provision of the Montana FCA.
- 338. Pursuant to the Montana FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties.

 Mont. Code Ann. § 17- 8-403(2).

Count XXII

Nevada Submission of False Claims To State Or Local Government Act Nev. Rev. Stat. §§ 357.010, et seq.

- 339. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 340. This is a civil action brought by Relators, on behalf of the State of Nevada, against Defendants under the State of Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.080(1).
- 341. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(a), creates liability for any person who, "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Nevada FCA.
- 342. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(b), creates liability for any person who, "Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent clam." Defendants have violated this provision of the Nevada FCA.
- 343. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(f), creates liability for any person who, "Knowingly makes or uses, or causes to be made or used, a false record or statement that is

material to an obligation to pay or transmit money or property to the State or a political subdivision." Defendants have violated this provision of the Nevada FCA.

- 344. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(g), creates liability for any person who, "Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State or a political subdivision." Defendants have violated this provision of the Nevada FCA.
- 345. The Nevada FCA, Nev. Rev. Stat. § 357.040(1)(i), creates liability for any person who, "Conspires to commit any of the acts set forth in this subsection." Defendants have violated this provision of the Nevada FCA.
- 346. Pursuant to the Nevada FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Nev. Rev. Stat. § 357.040(2).

Count XXIII

New Jersey False Claims Act N.J. Stat. Ann. §§ 2a:32c-1, et seq.

- 347. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 348. This is a civil action brought by Relators, in the name of the State of New Jersey, against Defendants pursuant to the State of New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-5.b.
- 349. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3(a) creates liability for any person who "[k]nowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the New Jersey FCA.

- 350. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3(b) creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State." Defendants have violated this provision of the New Jersey FCA.
- 351. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3(g) creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State." Defendants have violated this provision of the New Jersey FCA.
- 352. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3(c) creates liability for any person who "[c]onspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State." Defendants have violated this provision of the New Jersey FCA.
- 353. Pursuant to the New Jersey FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. N.J. Stat. Ann. § 2A:32C-3.

Count XXIV

New Mexico Medicaid False Claims Act N.M. Stat. Ann. §§ 27-14-1, et seq.

- 354. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 355. This is a civil action brought by Relators, on behalf of the State of New Mexico, against Defendants under the State of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7.B.
- 356. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4(A), creates liability for any person "presents, or causes to be presented, to the state a claim for payment under the medicaid

program knowing that such claim is false or fraudulent." Defendants have violated this provision of the New Mexico FCA.

- 357. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4(B), creates liability for any person "presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program." Defendants have violated this provision of the New Mexico FCA.
- 358. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4(C), creates liability for any person "makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false." Defendants have violated this provision of the New Mexico FCA.
- 359. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4(E), creates liability for any person "makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the medicaid program, knowing that such record or statement is false." Defendants have violated this provision of the New Mexico FCA.
- 360. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4(D), creates liability for any person "conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent." Defendants have violated this provision of the New Mexico FCA.
- 361. Pursuant to the New Mexico FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and such other relief as authorized. N.M. Stat. Ann. § 27-14-4.

Count XXV

New York False Claims Act N.Y. Fin. Law §§ 187, et seq.

- 362. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 363. This is a civil action brought by Relators, on behalf of the State of New York, against Defendants under the State of New York False Claims Act, N.Y. Fin. Law § 190(2).
- 364. The New York FCA, N.Y. Fin. Law § 189(1)(a), creates liability for any person who "knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the New York FCA.
- 365. The New York FCA, N.Y. Fin. Law § 189(1)(b), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the New York FCA.
- 366. The New York FCA, N.Y. Fin. Law § 189(1)(g), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government."

 Defendants have violated this provision of the New York FCA.
- 367. The New York FCA, N.Y. Fin. Law § 189(1)(h), creates liability for any person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a local government, or conspires to do the same."

 Defendants have violated this provision of the New York FCA.
- 368. The New York FCA, N.Y. Fin. Law § 189(1)(c), creates liability for any person who "conspires to commit a violation of" the law. Defendants have violated this provision of the New York FCA.

369. Pursuant to the New York FCA, Defendants is thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. N.Y. Fin. Law § 189(1).

Count XXVI

North Carolina False Claims Act N.C. Gen. Stat. §§ 1-605, et seq.

- 370. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 371. This is a civil action brought by Relators, on behalf of the State of North Carolina, against Defendants under the State of North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).
- 372. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(1), creates liability for any person "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the North Carolina FCA.
- 373. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(2), creates liability for any person "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the North Carolina FCA.
- 374. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(7), creates liability for any person "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendants have violated this provision of the North Carolina FCA.

- 375. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(3), creates liability for any person "[c]onspires to commit a violation of" the law. Defendants have violated this provision of the North Carolina FCA.
- 376. Pursuant to the North Carolina FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. N.C. Gen. Stat. § 1-607(a).

Count XXVII

Oklahoma Medicaid False Claims Act Okla. Stat. §§ 63-5053 (2007), et seq

- 377. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 378. This is a civil action brought by Relators, in the name of the State of Oklahoma, against Defendants pursuant to the State of Oklahoma Medicaid False Claims Act, Okla. Stat § 63-5053.2(B).
- 379. The Oklahoma FCA, Okla. Stat § 63-5053.1(B)(1), creates liability for any person who "[k]nowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Oklahoma FCA.
- 380. The Oklahoma FCA, Okla. Stat § 63-5053.1(B)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state." Defendants have violated this provision of the Oklahoma FCA.
- 381. The Oklahoma FCA, Okla. Stat § 63-5053.1(B)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement to

conceal, avoid, or decrease an obligation to pay or transmit money or property to the state."

Defendants have violated this provision of the Oklahoma FCA.

- 382. The Oklahoma FCA, Okla. Stat § 63-5053.1(B)(3), creates liability for any person who "[c]onspires to defraud the state by getting a false or fraudulent claim allowed or paid."

 Defendants have violated this provision of the Oklahoma FCA.
- 383. Pursuant to the Oklahoma FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Okla. Stat § 63-5053.1(B).

Count XXVIII

Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act P.R. Laws Ann. Tit 32, § 2934, et seq.

- 384. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 385. This is a civil action brought by Relators, in the name of the Commonwealth of Puerto Rico, against Defendants under the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act, P.R. Laws Ann. Tit. 32, § 2934a.
- 386. The Puerto Rico FCA, P.R. Laws Ann. Tit. 32, § 2934(1)(a), creates liability for any person "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval of benefits under any Government Program or under a service contract." Defendants have violated this provision of the Puerto Rico FCA.
- 387. The Puerto Rico FCA, P.R. Laws Ann. Tit. 32, § 2934(1)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under any Government Program or under a service contract." Defendants have violated this provision of the Puerto Rico FCA.

- 388. The Puerto Rico FCA, P.R. Laws Ann. Tit. 32, § 2934(1)(d), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property, relating to any Government Program or any service contract." Defendants have violated this provision of the Puerto Rico FCA.
- 389. The Puerto Rico FCA, P.R. Laws Ann. Tit. 32, § 2934(1)(d), creates liability for any person who "[c]onspires to commit a violation of" the law. Defendants have violated this provision of the Puerto Rico FCA.
- 390. Pursuant to the Puerto Rico FCA, Defendants are thus liable to the Commonwealth for statutorily defined damages sustained because of the acts of Defendants and civil penalties. P.R. Laws Ann. tit. 32, § 2934.

Count XXIX

Rhode Island False Claims Act R.I. Gen. Laws §§ 9-1.1-1, et seq.

- 391. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 392. This is a civil action brought by Relators, in the name of the State of Rhode Island, against Defendants pursuant to the State of Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).
- 393. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(1), creates liability for any person who "[k]nowingly presents, or causes to be presented a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Rhodes Island FCA.

- 394. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Rhodes Island FCA.
- 395. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendants have violated this provision of the Rhodes Island FCA.
- 396. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(3), creates liability for any person who "[c]onspires to commit a violation of" the law. Defendants have violated this provision of the Rhodes Island FCA.
- 397. Pursuant to the Rhode Island FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. R.I. Gen. Laws § 9-1.1-3(a).

Count XXX

Tennessee Medicaid False Claims Act Tenn. Code Ann. §§ 71-5-181, et seq.

- 398. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 399. This is a civil action brought by Relators, in the name of the State of Tennessee, against Defendants under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b)(1).

- 400. The Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l)(A), creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program." Defendants have violated this provision of the Tennessee FCA.
- 401. The Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l)(B), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program." Defendants have violated this provision of the Tennessee FCA.
- 402. The Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l)(D), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program." Defendants have violated this provision of the Tennessee FCA.
- 403. The Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l)(C), creates liability for any person who "[c]onspires to commit a violation of" the law. Defendants have violated this provision of the Tennessee FCA
- 404. Pursuant to the Tennessee FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Tenn. Code Ann. § 71-5-182(a).

Count XXXI

Texas Medicaid Fraud Prevention Act Tex. Hum. Res. Code § 36.001, et seq.

- 405. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 406. This is a civil action brought by Relators, in the name of the State of Texas, against Defendants under the State of Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code § 36.101(a).
- 407. The Texas FCA, Tex. Hum. Res. Code § 36.002(1), creates liability for any person who "knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized." Defendants have violated this provision of the Texas FCA.
- 408. The Texas FCA, Tex. Hum. Res. Code § 36.002(2), creates liability for any person who "knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized." Defendants have violated this provision of the Texas FCA.
- 409. The Texas FCA, Tex. Hum. Res. Code § 36.002(3), creates liability for any person who "knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received." Defendants have violated this provision of the Texas FCA.

- 410. The Texas FCA, Tex. Hum. Res. Code § 36.002(12), creates liability for any person who "knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program." Defendants have violated this provision of the Texas FCA.
- 411. The Texas FCA, Tex. Hum. Res. Code § 36.002(13), creates liability for any person who "knowingly engages in conduct that constitutes a violation under Section 32.039(b)." Defendants have violated this provision of the Texas FCA.
- 412. The Texas FCA, Tex. Hum. Res. Code § 36.002(9), creates liability for any person who "conspires to commit a violation" of the law. Defendants have violated this provision of the Texas FCA.
- 413. Pursuant to the Texas FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Tex. Hum. Res. Code § 36.052.

Count XXXII

Vermont False Claims Act 32 V.S.A. Chapter 7, Subchapter 8, et seq.

- 414. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 415. This is a civil action brought by Relators, in the name of the State of Vermont, against Defendants under the State of Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, § 632(b).

- 416. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(1), provides that no person shall "knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Vermont FCA.
- 417. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(2), provides that no person shall "knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Vermont FCA.
- 418. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(3), provides that no person shall "knowingly present, or cause to be presented, a claim that includes items or services resulting from a violation of 13 V.S.A. chapter 21 or section 1128B of the Social Security Act, 42 U.S.C. §§ 1320a-7b." Defendants have violated this provision of the Vermont FCA.
- 419. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(4), provides that no person shall "knowingly present, or cause to be presented, a claim that includes items or services for which the State could not receive payment from the federal government due to the operation of 42 U.S.C. § 1396b(s) because the claim includes designated health services (as defined in 42 U.S.C. § 1395nn(h)(6)) furnished to an individual on the basis of a referral that would result in the denial of payment under 42 U.S.C. chapter 7, subchapter XVIII (the "Medicare program"), due to a violation of 42 U.S.C. § 1395nn." Defendants have violated this provision of the Vermont FCA.
- 420. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(9), provides that no person shall "knowingly make, use or cause to be made or used, a false record or statement

material to an obligation to pay or transmit money or property to the State;." Defendants have violated this provision of the Vermont FCA.

- 421. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(10), provides that no person shall "knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State." Defendants have violated this provision of the Vermont FCA.
- 422. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(11), provides that no person shall "as a beneficiary of an inadvertent submission of a false claim to the State, or as a beneficiary of an overpayment from the State, and who subsequently discovers the falsity of the claim or the receipt of overpayment, fail to disclose the false claim or receipt of overpayment." Defendants have violated this provision of the Vermont FCA.
- 423. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(a)(12), provides that no person shall "conspire to commit a violation of this subsection." Defendants have violated this provision of the Vermont FCA.
- 424. Pursuant to the Vermont FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. 32 V.S.A. Chapter 7, Subchapter 8, § 631(b).

Count XXXIII

Virginia Fraud Against Taxpayers Act Va. Code Ann. §§ 8.01-216.1, et seq.

425. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.

- 426. This is a civil action brought by Relators, on behalf of the Commonwealth of Virginia, against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).
- 427. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(1), creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Virginia FCA.
- 428. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(2), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Virginia FCA.
- 429. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth." Defendants have violated this provision of the Virginia FCA.
- 430. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(3), creates liability for any person who "conspires to commit a violation of" the law. Defendants have violated this provision of the Virginia FCA.
- 431. Pursuant to the Virginia FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Va. Code Ann. § 8.01-216.3(A).

Count XXXIV

Washington State Medicaid Fraud False Claims Act Wash. Rev. Code §§ 74.66.005, et seq

- 432. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 433. This is a civil action brought by Relators, on behalf of the State of Washington, against Defendamts under the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.050(1).
- 434. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(a), creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Defendants have violated this provision of the Washington FCA.
- 435. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Defendants have violated this provision of the Washington FCA.
- 436. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(g), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government entity, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government entity." Defendants have violated this provision of the Washington FCA.
- 437. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(c), creates liability for any person who "[c]onspires to commit one or more of the violations in this subsection (1)." Defendants have violated this provision of the Washington FCA.

438. Pursuant to the Washington FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Wash. Rev. Code § 74.66.020(1).

Count XXXV

Wisconsin False Claims for Medical Assistance Act Wis. Stat. § 20.931, et seq.

- 439. Relators incorporate by reference the preceding paragraphs as though fully set forth herein.
- 440. This is a civil action brought by Relators, on behalf of the State of Wisconsin, against Defendants under the State of Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931(5)(a), for acts occurring prior to the non-retroactive repeal of that law effective July 14, 2015.
- 441. The Wisconsin FCA, Wis. Stat. § 20.931(2)(a), creates liability for any person who "[k]nowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance." Defendants have violated this provision of the Wisconsin FCA.
- 442. The Wisconsin FCA, Wis. Stat. § 20.931(2)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance." Defendants have violated this provision of the Wisconsin FCA.
- 443. The Wisconsin FCA, Wis. Stat. § 20.931(2)(g), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance program." Defendants have violated this provision of the Wisconsin FCA.

- 444. The Wisconsin FCA, Wis. Stat. § 20.931(2)(c), creates liability for any person who "[c]onspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program." Defendants have violated this provision of the Wisconsin FCA.
- 445. Defendants have violated each of these provisions of the Wisconsin FCA, with respect to conduct and claims prior to July 14, 2015.
- 446. Pursuant to the Wisconsin FCA, Defendants are thus liable to the State for statutorily defined damages sustained because of the acts of Defendants and civil penalties. Wis. Stat. § 20.931(2).

VIII. PRAYERS FOR RELIEF

WHEREFORE, Relators pray for judgment against Defendants as follows:

- A. That Defendants are enjoined from violating the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. and the State FCAs;
- B. That judgment be entered against Defendants and in favor of the United States and the Relators in an amount equal to three times the amount of damages caused by Defendants' misconduct, as well as a civil penalty for each FCA violation in the maximum statutory amount;
- C. That judgment be entered against Defendants and in favor of the *Qui Tam* States and the Relators in the amount of the damages sustained by the *Qui Tam* States multiplied as provided for in the State FCAs, plus civil penalties in the ranges provided by the State FCAs;
- D. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

- E. That judgment be granted for Relators against Defendants for all costs, including, but not limited to, court costs, litigation costs, expert fees, and all attorneys' fees permitted under 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs;
- F. That Relators be awarded the maximum amount permitted under 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs; and,
 - H. That the Court award such other relief as the Court deems proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Relator requests a jury trial.

December 10, 2019

Respectfully submitted,

/s/ Suzanne E. Durrell

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