UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

United States of America *ex rel.* John Slowik, the State of California *ex rel.* John Slowik, the State of Colorado *ex rel.* John Slowik, the State of Connecticut *ex rel.* John Slowik, the State of Delaware *ex rel.* John Slowik, the State of Florida *ex rel.* John Slowik, the State of Georgia *ex rel.* John Slowik, the State of Hawaii *ex rel.* John Slowik, the State of Illinois *ex rel.* John Slowik, the State of Indiana *ex rel.* John Slowik, the State of Iowa *ex rel. John Slowik*, the State of Louisiana *ex rel.* John Slowik, the Commonwealth of Massachusetts *ex rel.* John Slowik, the State of Maryland *ex rel.* John Slowik, the State of Minnesota *ex rel.* John Slowik, the State of Michigan *ex rel.* John Slowik, the State of Montana *ex rel.* John Slowik, the State of Nevada *ex rel.* John Slowik, the State of New Hampshire *ex rel.* John Slowik, the State of New Jersey *ex rel.* John Slowik, the State of New Mexico *ex rel.* John Slowik, the State of New York *ex rel.* John Slowik, the State of North Carolina *ex rel.* John Slowik, the State of Oklahoma *ex rel.* John Slowik, the State of Rhode Island *ex rel.* John Slowik, the State of Tennessee *ex rel.* John Slowik, the State of Texas *ex rel.* John Slowik, the Commonwealth of Virginia *ex rel.* John Slowik, the State of Washington *ex rel.* John Slowik, the State of Wisconsin *ex rel.* John Slowik, the District of Columbia *ex rel.* John Slowik, and John Slowik individually,

Plaintiffs,

v.

OLYMPUS AMERICA, INC., OLYMPUS CORPORATION, OLYMPUS MEDICAL SYSTEMS CORP.,
GYRUS GROUP PLC, and
GYRUS ACMI,

Defendants.

Honorable Jose L. Linares

CASE NO.: 10-5994 (JLL)

FILED *IN CAMERA* AND UNDER SEAL

JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT
(Operative)

Plaintiff-Relator John Slowik ("Relator" or "Plaintiff")), by and through his undersigned attorneys, KENNEY & McCAFFERTY, P.C., on behalf of the United States of America, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Maryland, the State of Minnesota, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Washington, the State of Wisconsin, and the District of Columbia (the states and the District of Columbia shall hereinafter be referred to as the "Plaintiff States") alleges as follows against Olympus America, Inc. ("Olympus America" or "OCA"), Olympus Corporation ("Olympus Corp"), Olympus Medical Systems Corp. ("Olympus Medical")[1], Gyrus Group PLC ("Gyrus") and Gyrus ACMI ("Gyrus ACMI")[2] based upon personal knowledge and relevant documents:

1. This is an action brought on behalf of the United States of America and the Plaintiff States by Relator against Olympus and Gyrus pursuant to the *Qui Tam* provisions of the Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), referred to herein as the "Action."

2. The Relator in this Action is a former employee of Olympus. He worked for Olympus for eighteen (18) years in various executive positions, culminating in his appointment to the newly formed position of Chief Compliance Officer of Olympus America in February

[1] Olympus America, Olympus Corp and Olympus Medical shall hereinafter collectively be referred to as Olympus.
[2] Gyrus and Gyrus ACMI shall hereinafter collectively be referred to as Gyrus.

2009. Upon his appointment as Compliance Officer, Relator immediately attempted to eliminate the illegal and systemic practices described below. Relator was retaliated against, harassed and met severe resistance during his tenure as Compliance Officer.

3. As a direct, proximate and foreseeable result of Olympus', Gyrus', and Gyrus ACMI's (collectively "Defendants") fraudulent course of conduct set forth herein, and implemented on a national scale, Defendants knowingly submitted and/or caused to be submitted thousands of false or fraudulent statements, records, and claims to Medicare, Medicaid and other publicly-funded healthcare programs seeking reimbursement for health care services from at least 2000 through the present. Defendants also caused the submission of false Hospital Cost reports to these programs during the same time period, as is alleged *infra*.

4. Defendants' unlawful conduct described herein includes causing providers to submit false or fraudulent statements, false certifications of compliance with the Anti-Kickback Statute in cost reports, and false claims to government-funded healthcare programs. The false or fraudulent statements, certifications, and claims were relied upon by government-funded healthcare programs such as Medicare and Medicaid, and formed the basis for reimbursement and payments from such publicly-funded programs.

5. The schemes that have resulted in false claims submissions to Medicare and other government-funded healthcare programs which began in 2000 and which continue through the present, as alleged more specifically *infra*, include but are not limited to the following:

- Adopting and continuing Gyrus' practice of paying illegal remuneration to physicians and hospitals in the form of free medical equipment and/or providing discounted products with the intent to induce these physicians and hospitals to buy Gyrus' consumables following Olympus's acquisition of Gyrus in 2008. Olympus, as Gyrus' successor in interest, is liable to the Government Plaintiffs for damages which flow from the false claims submissions and false records submitted or caused to be submitted by Gyrus prior the acquisition

- Paying Gyrus sales representatives stipends of up to $2,300 per month without requiring any record keeping. The culture at Olympus was to keep customers "happy" through lavish entertainment activities, including expensive meals and outings. Accordingly, sales representatives used these generous stipends to fund extravagant physician entertainment activities. Gyrus failed to mandate record keeping requirements of such expenditures with the purpose and intent to conceal its physician entertainment activities.

- Paying physicians tens of thousands of dollars and sometimes more than $100,000.00 per year ostensibly for consulting services. These payments were in reality a *qui pro quo* to increase purchases of Olympus products. Indeed, consulting payments were based on the discretion of sales and marketing representatives with management's encouragement, endorsement and approval. Said payments were based entirely on sales potential, and irrespective of fair market value of services provided. In many cases there was no written consulting agreement to memorialize the terms of the consulting services. Olympus America instituted this sham physician consultant program with the specific intent to induce sales of its products by key accounts. Oftentimes Olympus America entered into sham consulting agreements to promote off-label uses of Olympus America products.

- Offering and/or paying illegal remuneration to physicians and hospitals, in the form of millions of dollars worth of free medical equipment. Categorized as various euphemisms including without limitation, "permanent loans," "leases," "promotions," "demo units," "MLS – Medical Loaner Scopes," "samples" and "trade-ins" this equipment was given away and written off with the intent to induce purchases of Olympus America's equipment, devices and supplies. In addition, Olympus America utilized the improper gifting of capital equipment and consumables to gain market share in an unlawful, anticompetitive manner. This practice enabled Olympus America to acquire monopoly power in certain segments of the medical business ultimately resulting in customers paying inflated prices which in turn were passed on to Government-funded healthcare programs.

- Using "honorarium" or "speaker" fees for physician marketing. Approved by management, they were ostensibly compensation to physicians for agreeing to speak at a formal speaking engagement. In reality, the speaker fees and honoraria were kickbacks intended to induce purchases of Olympus America products and/or to influence such purchases by the physician-speakers' peers. In accord with its speaker program, in many cases there was no written agreement to memorialize the terms of the speaker services.

- Giving away hundreds of thousands of dollars in "grants" to physicians and medical facilities ostensibly for an educational program or research

program. With the approval of management, the grants have actually been used to provide kickbacks to physicians and companies to do whatever they wanted with the money, in return for business. A grant committee established at Olympus America was comprised solely of sales, marketing and customer relation personnel. Relator participated in grant committee meetings starting in February 2009 and witnessed during those meetings that the grant approval process was based solely on the amount of sales that would be generated from the customer from the receipt of a grant. Relator's prompt overhaul of the grant approval process was met with harsh resistance from Olympus America management, including the termination of the Olympus America employee Relator appointed to head the reconstituted grant committee, under the pretext of job performance issues.

- Entertaining physicians, and sometimes their spouses, with lavish meals, golf, and other entertainment activities, such as the Olympus-sponsored U.S. Open of golf at Bethpage Black in New York and the U.S Open of tennis held in Fleshing Meadows, New York. During the time he oversaw the audit department, Relator was told by the Olympus America CEO not to enforce Olympus America's purported $100 meal limit rule.

- Giving physicians, and sometimes their spouses, luxury all-expense paid vacations to exotic international destinations, including Asia (especially Japan), Europe and Australia, in exchange for the promotion and use of Olympus products. Trips to Japan for physicians and their spouses were routine. Olympus and Olympus America spared no expense in entertaining on these luxury vacations, including such extravagances as a "traditional Japanese meal." Spouses of physicians were greeted by official Olympus personnel who personally saw to their attention.

- Using a charitable foundation to give away hundreds of thousands dollars annually. This independent legal charitable foundation funded solely by Olympus was overseen by a long time Olympus America employee named Hiroshi Ichikawa, who was responsible for customer relations. Ichikawa, along with three doctors who also happened to be Olympus VIP customers, Dr. Peter Cotton, Dr. Michael Sivak and Dr. Charlie Lightdale, had complete decision-making authority. These doctors were paid for their "work" for the foundation, albeit with no written contractual agreement. One perk that the doctors enjoyed was golf and dining with the CEO at the exclusive and private Saucon Valley Country Club where Mark Gumz, President and Chief Executive Officer, Olympus America, was a member.

- Defendants have unlawfully paid millions of dollars in kickbacks and bribes to customers all across the United States in exchange for new business or in exchange for continuing to purchase Defendants' medical products, which has caused the submission of claims for reimbursement that are false because they are tainted by kickbacks. In addition, certain of

> Defendants' customers, in particular most hospitals, that accepted Defendants' kickbacks in exchange for new or continuing business in turn have submitted thousands of Form 2552 cost reports and interim claims to government-funded health care programs to recoup some or all of the cost of the purchase of Defendants' products. Significantly, federal law mandates that providers submit such cost reports annually. These cost reports contained false certification of compliance with the Anti-Kickback Statute, which is a condition of payment by government-funded healthcare programs such as Medicare. By paying kickbacks and bribes in violation of the AKS, Defendants caused their customers' certifications to be false. As a result, all interim and final claims for payment submitted to government-funded healthcare programs by those customers were tainted and rendered false in violation of the False Claims Act.

6. By these actions and the other actions detailed herein, Defendants, acting with the requisite scienter, have violated several laws, including without limitation, the FCA and the Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute ("AKS"). Olympus' violations of the AKS give rise to liability under the FCA. The purpose of giving away medical equipment, wining and dining physicians, and paying physicians exorbitant speaker fees, consulting fees and honoraria was to gain market share at inflated prices, as well as to induce hospitals and physicians to purchase additional equipment, supplies, and/or consumables from Olympus and/or later, from Gyrus. The physicians, or the hospitals with which these physicians affiliate, in turn submitted claims to Medicare and Medicaid for procedures performed with Olympus medical equipment, bringing the Olympus financial inducements within the ambit of the AKS.

7. Defendants' unlawful conduct has had a dramatic negative financial impact on Medicare, Medicaid, other government-funded healthcare programs and the government fisc.

8. For example, the federal government, primarily through Medicare and Medicaid, pays for billions of dollars in medical supplies, medical devices and equipment and

services. Defendants knew the federal government would ultimately pay for a large portion of its medical products sold to their customers. Defendants also knew that certain of their customers would seek payment from government health care programs through interim claims and cost reports. Defendants also knew that their customers were required to certify compliance with the AKS on cost reports as a condition of payment, and that their kickbacks would cause the cost reports to be false. As such, Defendants are liable under the FCA for knowingly causing customers to submit false certifications of compliance with the AKS and to submit false claims to get government funds paid or approved by the United States.

9. Defendants' unlawful conduct, in particular its unlawful inducements to physicians, extends beyond the United States. As is described below, Defendants' unlawful conduct implicates the Foreign Corrupt Practices Act ("FCPA"). Relator discovered almost immediately in his role as Compliance Office that the company's scheme to bribe physicians through, *inter alia*, lavish entertainment activities, trips, meals, expenses, with the purpose and intent to increase sales, tainted the company's sales and marketing activities on an international scale, including in Canada, Mexico and Latin America.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e)(4)(A), there has been no statutorily relevant public disclosure of substantially the same "allegations or transactions" alleged in this Action. Even to the extent there has been any such public disclosure, Relator meets the definition of an original source, as that term is defined under 31 U.S.C. §3730(e)(4)(B)[3]. Specifically, Relator voluntarily disclosed to the Government the information upon which allegations or transactions at issue in this Action are based prior to any purported public disclosure under 31 U.S.C. §§3730(e)(4)(A). Alternatively, Relator has knowledge that is independent of and materially adds to any purported publicly disclosed allegations or transactions, and, Relator voluntarily provided the information to the Government before this complaint was filed. Relator therefore qualifies as an "original source" of the allegations in this Action such that the so-called public disclosure bar set forth at 31 U.S.C. §3730(e)(4) is inapplicable.

11. Relator shall concurrently serve upon the Attorney General of the United States and the United States Attorney for the District of New Jersey this complaint and a written disclosure summarizing the known material evidence and information in the possession of Relator related to this Action, in accordance with the provisions of 31 U.S.C. §3730(b)(2). The

[3] In March 2010, Congress enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, § 10104(j)(2), 124 Stat. 119 (2010), which contained amendments to FCA's definition of an "original source" set forth in 31 U.S.C. §30730(e)(4)(A). To the extent § 30730(e)(4)(A) as amended by PPACA is deemed to be retroactive, and to the extent that there has been a public disclosure unknown to Relator, Relator meets the definition of an original source as that term is more broadly defined in the PPACA.

disclosure statement is supported by material evidence, and documentary evidence has been produced with the disclosure. The documents referenced in the disclosure statement, and those produced in connection therewith, are incorporated herein by reference.

12. This Court has personal jurisdiction and venue over Olympus pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because those sections authorize nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, Defendants can be found in, reside, and transact business in this District.

13. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the Defendants transact business in this judicial district, and acts proscribed by 31 U.S.C. §3729 have been committed by Defendants in this District. Therefore, venue is proper within the meaning of 28 U.S.C. §1391(b) and (c) and 31 U.S.C. §3732(a).

PARTIES

14. The real party in interest to the FCA *Qui Tam* claims herein is the United States of America. Accordingly, at this time, Relator is pursuing this Action on behalf of, *inter alia*, the United States on the FCA *Qui Tam* claims set forth herein. *See, e.g.*, 31 U.S.C. § 3730(b)(1). The Plaintiff States are the real parties in interest to *Qui Tam* claims brought under state law. Accordingly, Relator is pursuing the state law claims on behalf of the Plaintiff States.

15. Relator John Slowik is a resident of Pennsylvania. Mr. Slowik has been employed by Olympus America from 1991 through September 8, 2010 in various capacities, including most recently as the Chief Compliance Officer.

16. Defendant Olympus Corp is a Japan-based company that manufactures optics and imaging products. Olympus is headquartered in Tokyo, Japan. Olympus stock is traded on the Tokyo Stock Exchange. The Representative Director and President of Defendant Olympus is

Tsuyoshi Kikukawa. Defendant Olympus Corp is liable for the acts of its wholly-owned subsidiaries for the unlawful conduct identified herein, including Olympus America and Olympus Medical.

17. Defendant Olympus Medical is a Japan-based company that manufactures endoscopes, biliary stents and other medical devices. Olympus is headquartered in Tokyo, Japan. The Representative Director and President of Defendant Olympus Medical Systems Corp. is Haruhito Morishima.

18. Defendant Olympus America is the American arm of the Olympus global conglomerate with corporate headquarters situated at 3500 Corporate Parkway, Center Valley, PA 18034. The President and CEO of Defendant Olympus America during Relator's tenure was Mark Gumz. Gumz was also Relator's former direct supervisor. Defendant Olympus America goes by the corporate name Olympus Corporation of the Americas.

19. Defendant Gyrus Group PLC ("Gyrus") is a U.K. medical equipment company that an Olympus wholly owned subsidiary acquired in February, 2008. Upon Olympus' acquisition of Gyrus for a total purchase price of approximately ¥ 2 billion (210 billion yen) in cash, Gyrus became a wholly owned subsidiary of Olympus. This was the largest acquisition in Olympus' history, almost four times its previous most costly purchase.

20. By virtue of its acquisition of Gyrus and its retention of senior Gyrus management, Olympus assumed liability for Gyrus' pre-acquisition operations as successor in interest. Olympus is liable for the unlawful conduct that has seamlessly continued post acquisition. Gyrus has annual sales of approximately $600 million.

21. Gyrus had previously acquired ACMI ("Gyrus ACMI") in 2005, thereby instantly doubling the group's value and strengthening its position in the U.S. market for urological and gynecological surgical tools.

22. Gyrus ACMI grew sales in the U.S. that eventually accounted for more than 80% of its parent company's global revenues.

23. Gyrus operates as Gyrus ACMI in the US, where it does most of its business.

24. According to Olympus Corp's 2009 Annual Report, Gyrus "has unique energy-related processing devices as its mainstay product lineup."

25. Olympus has two business segments: an Imaging Systems Business centered on digital cameras, optical components and voice recorders; and a Medical Systems Business, whose core products include both gastroenterological and surgical endoscopes, endotherapy devices, endoscopic ultrasound systems, medical information systems and biliary stents.

26. Current and former Olympus executives with knowledge of the fraudulent activities alleged herein include F. Mark Gumz, former President and Chief Executive Officer, Olympus America; Karl Watanabe, Former VP Treasurer and Chief Japanese US executive Olympus America; Rick Harbuck, VP Sales, Olympus America; John Temple, VP Sales, Olympus America; Charlie Goodwin, VP Sales, Gyrus; Hiroshi Ichikawa, former Chief Customer Relations, Olympus America and Yukio Nakajima, Director of Customer and Business Relations, Olympus America.

27. According to Olympus Corp.'s 2009 Annual Report, "[c]ore products in the Medical Systems Business include both gastroenterological and surgical endoscopes, endotherapy devices, endoscopic ultrasound systems and medical information systems."

28. The Annual Report also states that "Sales in the Medical Systems Business in fiscal 2009 grew 8.7% year on year to ... $4,040 million...." That is, Olympus sales in the Medical Systems Business alone in 2009 were approximately $4 billion.

29. Further, the Report states that "the Medical Systems Business recorded increased revenue due to healthy sales of mainstay products in its gastrointestinal and surgical endoscope lineups as well as the inclusion of the results of Gyrus Group . . . in Olympus's scope of consolidation from February 2008."

30. However, Olympus Corp's Annual Report also states that "because more than 70% of sales in this business were in North America and Europe, the unfavorable impact of foreign currency exchange rates drove down profit."

GOVERNMENT-FUNDED HEALTHCARE PROGRAMS DAMAGED BY OLYMPUS' UNLAWFUL CONDUCT

A. Medicare

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

18. Medicare was designed to be a health insurance program and to provide for the payment of, *inter alia*, hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age, and for certain others that qualify under the terms and conditions of the Medicare Program. Individuals who receive benefits under Medicare are commonly referred to as "beneficiaries."

19. The Medicare program is divided into 3 parts, two of which are relevant here. Part A of the Medicare program authorizes payment for institutional care, including inpatient hospital care and related services. See 42 U.S.C. §§1395c-1395i-5. Part B of the Medicare program covers services provided by physicians, certain pharmaceutical products, diagnostic tests and other medical services not covered by Part A.

20. Reimbursement for Medicare claims under Medicare Part A is made by the United States through CMS which contracts with private insurance carriers known as fiscal intermediaries ("FIs") to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the FIs act on behalf of CMS.

21. In the case of Part B, CMS contracts with "carriers" who have the same or similar functions as the FIs for Part A. *See* 42 U.S.C. §1395u.

22. Upon discharge from a hospital, the hospital submits an interim reimbursement claim for items and services provided to that patient. These claims are submitted on a standard form, the hard copy version is the CMS-1450 and the electronic copy is the UB-92. For Part B services, a health care provider submits a claim for reimbursement using standard form CMS-1500.

23. The most basic requirement for reimbursement eligibility under Medicare is that the service provided must be reasonable and medically necessary. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

24. Medicare requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute, *infra,* and with

other federal laws governing the provision of health care services in the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

25. In other words, CMS will not pay the claim if a provider tells CMS or its agent that it provided goods or services: in violation of the AKS; that were not medically unnecessary; that were performed solely for the profit of the provider; and/or, that violated another relevant law.

B. Other Programs Harmed

26. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the federal government and those state governments choosing to participate in the program. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

27. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

28. FEHBP plans are managed by the Office of Personnel Management.

29. In addition to Medicare, Medicaid and FEHBP, the federal government reimburses for medical services, supplies and devices under several other health care programs,

including but not limited to the Railroad Retirement Medicare Program, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, *et seq.*, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities. Coverage under these programs mirrors under the Medicare and Medicaid programs.

30. For the purposes of the false claims submissions at issue in this case, the rules surrounding reimbursement under Medicaid, FEHBP, the Railroad Retirement Medicare Program, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, *et seq.*, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities closely align with the rules and regulations governing Medicare reimbursement. Each of the government-funded healthcare programs identified in this Action requires every provider who seeks payment from a program to certify compliance with the Anti-Kickback Statute as is set forth *infra*.

APPLICABLE FEDERAL LAWS AND REGULATIONS

A. The False Claims Act

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

46. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a

violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

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

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

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

50. The FCA, 31 U.S.C. § 3729(b)(4) provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." A violation of the Anti-Kickback Statute, *see infra*, is material to the government's decision to pay, and a violation of the Anti-Kickback Statute renders resulting claims to Medicare false or fraudulent in violation of the FCA. Moreover, the Patient Protection

and Affordable Care Act, Publ. L No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010), described *infra* makes clear violations of the AKS give rise to liability under the FCA.

B. The Anti-Kickback Statute

51. The Medicare and Medicaid Patient Protection Act, also known as the AKS or the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

52. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the AKS was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must

commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

53. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

54. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

55. 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).

56. A recipient of remuneration is also liable under the AKS, 42 U.S.C. §1320a-7(b)(1), if he or she:

> "knowingly and willfully, solicits or receives any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or in return for purchasing, leasing, ordering, or arranging for or recommending 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"

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

58. Accordingly, under this statute, medical device/equipment manufacturers such as Defendants may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians or hospitals or others to order or recommend products or procedures that may be paid for by a federally-funded healthcare programs such as Medicare.

59. The Anti-Kickback Statute not only prohibits outright bribes, but also prohibits any payment or other remuneration by a manufacturer to a physician or other person or entity which has as one of its purposes the inducement of the physician to perform procedures using the manufacturer's products or to induce the physician to influence or recommend use of the manufacturer's product.

60. The Patient Protection and Affordable Care Act, Publ. L No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010) ("PPACA"), which became law on March 23, 2010, leaves no doubt that violations of the AKS give rise to a violation of the FCA, by providing: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." In other words, pursuant to the PPACA, claims for items or services billed to government-funded healthcare programs (including Medicare) "resulting from" a violation of the anti-kickback statute are "false or fraudulent claims" under the FCA.

61. The PPACA also clarified the intent requirement for the AKS, and now provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation." Accordingly, proof that a defendant knew of and specifically intended to violate the AKS is no longer required, instead proof that the defendant intended to perform the actions that violated the anti-kickback statute gives rise to a violation.

62. At all times relevant to this complaint, compliance with the Anti-Kickback Statute has been a condition to participation for a health care provider under Medicare, Medicaid and other federally-funded healthcare programs. Moreover, compliance with the AKS is a *condition of payment* for claims made to such programs for reimbursement for services.

63. For example, under 42 U.S.C. § 1395y(a)(1)(A), "nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury."

64. Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

65. As set forth below, Olympus and Gyrus have and continue to provide kickbacks routinely in cash and in kind to physicians and hospitals to induce: physicians to perform procedures using their products; physicians to promote their products; and, hospitals to purchase their products.

66. By definition pursuant to the PPACA and firmly established law prior to the clarifications set forth therein, Olympus' and Gyrus' violations of the Anti-Kickback Statute have rendered all claims for procedures performed by a physician or hospital who has been offered or accepted such kickbacks false as that term is defined by the FCA.

67. Olympus and Gyrus are liable for causing the submission of these false claims.

68. In addition, certain providers, such as hospitals, participating in federal healthcare programs must annually certify compliance with the AKS. This certification is included in the CMS Form 2552 cost report that such providers submit each year. The federal Medicare program and the state Medicaid programs rely upon this certification in making payments to such providers. The "advisory" language preceding the certification section reads as follows:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, **IF SERVICES IDENTIFIED BY THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK** OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES, AND/OR IMPRISONMENT MAY RESULT.

(Capital emphasis in original; bolded emphasis added)

The specific certification language reads:

> CERTIFICATION BY OFFICER OR ADMINISTRATOR OR PROVIDER(S)
>
> I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [Provider Name(s) and Number(s)] for the cost reporting period beginning [date] and ending [date] and that to

> the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. **I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.**

(Capital emphasis in original; bolded emphases added)

38. Payment to Providers under federal healthcare programs - not just participation in those programs - is conditioned upon this express certification that the Provider has complied with the AKS. Providers' suppliers are also bound by the rules and regulations underlying the AKS. *See* 42 C.F.R. § 1001.952(h)(2). Thus, the CMS Form 2552 cost reports submitted to Medicare and Medicaid programs by any Provider receiving kickbacks from Defendants were false for purposes of the FCA because they contained a false certification of AKS compliance.

40. The discount "safe harbor" to the AKS applies to certain narrow forms of payment (*see* 42 U.S.0 § 1320a-7b(b)(3)(A) and (b)(3)(E); 42 C.F.R. § 1001.952(h)), but Relator does not bear the burden of alleging or proving inapplicability of the discount safe harbor as an element of the claims pleaded herein. Moreover, as set forth below, the discount safe harbor does not apply to any of the payments comprising Defendants' illegal inducement schemes.

41. None of Defendants' kickbacks met the constraints of the regulatory safe harbor. Specifically, all of Defendants' kickbacks violated one or more of the safe-harbor's requirements that a payment (1) is an arms-length reduction in the amount a buyer was charged (§ 1001.952 (h)(5)); (2) with terms fixed at the time of the initial purchase ((h)(4)); (3) paid by check ((h)(5)(i)); (4) fully and accurately reported on the invoice or statement submitted to the buyer at the time of sale ((h)(2)(ii)(A, B)); (5) followed by documentation of the discount's calculation and the specific goods purchased to which it applied ((h)(2)(ii)(B)); and (6)

with a calculation period that left the buyer unimpeded to comply with its obligations to earn the full payment within a single fiscal year, to fully and accurately report the discount to the government, and to do so for the year in which the payment was earned ((h)(2)(ii)(A, B); (h)(1)(ii)(A-C)).

C. The Stark Law - The Medicare/Medicaid Self-Referral Statute

69. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn, *et seq.*, known as the "Stark" law, prohibits a physician from making a referral that will lead to a claim being submitted for "designated health services," the definition of which encompasses services rendered using equipment manufactured by Olympus and Gyrus, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. §1395nn(a)(1), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such prescriptions.

70. Stark also prohibits payment of claims rendered in violation of its provisions. 42 U.S.C. §13951m(a)(1), (g)(1).

ALLEGATIONS

A. Olympus' Long History of Fraudulent Conduct

71. Olympus has a long history of noncompliance and fraudulent conduct.

72. By way of example, when Relator joined Olympus approximately twenty years ago, Olympus intentionally failed to file sales tax returns and encouraged customers to have products shipped to other locations to avoid sales tax. This was a nationwide practice. Relator insisted that Olympus change processes to collect and remit sales taxes to all state and local governments.

73. Then, in 1996, Olympus settled a VA contract for fraudulent conduct in the amount of $25,000,000 for overcharging customers. Olympus intentionally overcharged VA hospitals for years to increase profits. Relator assumed responsibility for Government Contract Compliance in 1997 and implemented a strict program that ensured compliance and disclosure through the remainder of his employment.

74. Again, in 2002, Olympus entered into an immunity agreement with the FDA criminal law enforcement unit based on theft by Olympus sales representatives from Olympus customers. Specifically, Relator, while in charge of internal audit, discovered a conspiracy among more than fifty (50) managers, current sales representatives and former sales representatives to steal equipment from customers and Olympus, which in turn was sold for personal gain or was provided to key customers as gifts to induce sales. Initially Relator was discouraged from pursuing this misconduct, until he voluntarily called FDA Criminal enforcement to request assistance.

75. Olympus acquired a series of industrial Companies during 2002 through 2007 collectively known as Olympus Non Destructive Testing "ONDT." ONDT had numerous contracts with the General Service Administration ("GSA") pursuant to which ONDT products were purchased by the government. Relator questioned the billings to the Government under these contracts as well as willful concealment of significant product discounts offered only to non-government customers. This was met with a high level of resistance from management at ONDT and executive Japanese management. Nevertheless, Relator insisted on disclosing improper billing practices to the Government in 2009, and Relator resolved the pricing issues in collaboration with GSA.

76. Notwithstanding this history of fraudulent conduct, Olympus had no compliance department until February, 2009.

B. Relator's Background with Olympus

77. Relator began working for Olympus in 1991.

78. From 1991 through 1994, Relator served as a Finance Manager primarily responsible for handling tax fraud cases.

79. From 1994 through 1997, Relator became the Director of Operations for Olympus Image Systems, and was responsible for ITS, Finance, Operations, Planning and Human Resources.

80. From 1997 through 2004, Relator became the Executive Director of Internal Audit. In this capacity, Relator worked with the FDA and the FBI in solving and settling significant cases of internal thefts of medical equipment. Relator was responsible for ensuring all Company policies and procedures were followed. This mandate had one clear exception; compliance with company ethics policies, including compliance with the Anti-kickback statute and the False Claims Act.

81. From 2004 through 2008, Relator's responsibilities increased yet again and he was promoted to the Vice President of Treasury. In this position, Relator handled special projects for the company such as construction of the corporate headquarters and interim head of integration business.

82. From 2009-2010, Relator acted as the Vice President of Government/Regulatory Compliance/Chief Compliance Officer. Prior to 2009, Olympus, a highly sophisticated corporation *had no Compliance Department*.

83. Former Olympus America President and CEO Mark Gumz formally announced Relator's appointment as Chief Compliance Officer in a Memorandum disseminated companywide on January 23, 2009. Gumz described the position as a "new function" and that Relator "will have oversight of compliance responsibilities for all OCA companies."

84. Pursuant to Gumz's memorandum, Relator's primary responsibilities included "developing, implementing and overseeing the Olympus Compliance Program which includes policies and procedures relating to: (a) the federal Anti-Kickback Statute; (c) the False Claims Act and any U.S. State Law, (d) the Food, Drug and Cosmetic Act,....(e) the Foreign Corrupt Practices Act and any U.S. State law.... (j) grants and charitable donations,...." among many other things.

85. In the foregoing, Gumz effectively admits not only that Olympus lacked a Compliance Department, but that it had absolutely no policies or procedures in place relating to the FCA, the AKS and the FCPA prior to January 23, 2009.

86. Relator was, quite literally, tasked with starting a Compliance Program from scratch, yet Relator had no *legal training, much less a background in healthcare compliance.* Nevertheless, Olympus did not even suggest that Relator seek the extensive training required to develop and run the international company's Compliance Department. Instead, Relator, acting on the belief at the time that Olympus America executives truly intended to bring the company into compliance, took it upon himself to research the position and to seek out training about healthcare laws.

87. Just as astounding, despite the overwhelming breadth of the position tasked to Relator, Gumz deprived him of the necessary funding or staffing to effectively fulfill his

appointed duties. The entire Olympus America Compliance Department was comprised of merely two individuals: Relator and Ken Turner.

88. Turner, like Relator, was not a lawyer and had no background in healthcare compliance.

C. Gyrus Group PLC and Gyrus ACMI – Acquisition by Olympus in 2008

89. In February 2008, Olympus, through a subsidiary, acquired Gyrus Group PLC ("Gyrus") for approximately $2 billion. The unlawful conduct complained of herein was firmly entrenched in the Gyrus business model prior to the Olympus acquisition, and continued unabated following the acquisition with the full knowledge and endorsement by Olympus executive management.

90. Gyrus is a U.K. medical equipment company that is headquartered in Boston, Massachusetts.

91. Gyrus includes Gyrus ACMI. In 2005, Gyrus acquired ACMI, instantly doubling the group's value and significantly strengthening its position in the U.S. market for urological and gynecological surgical tools.

92. Upon information and belief, Gyrus operates as Gyrus ACMI in the US, where it does most of its business.

93. According to Olympus' Annual Report, Gyrus "has unique energy-related processing devices as its mainstay product lineup."

94. By acquiring Gyrus, Olympus intended to expand its market share for urology endoscopes in Japan, the Americas, and Europe to a 50% share.

95. Hereinafter the term Gyrus shall refer collectively to Gyrus PLC and Gyrus ACMI.

96. Significantly, Olympus's acquisition of Gyrus was at the center of an accounting scandal that former Olympus Corp President and CEO Michael Woodford exposed publicly in October 2011.

D. Gyrus' Kickback Scheme

97. Like Olympus, at the time of the acquisition, Gyrus had no Compliance Department and very little oversight.

98. The entire business model at Gyrus revolved around kickbacks. That is, Gyrus sales representatives routinely gave away medical equipment, including large, expensive generators valued at approximately $20,000. This equipment was given to hospitals and physicians for free.

99. The purpose of providing this equipment to customers at deeply discounted prices or for free was to induce the hospitals and physicians to purchase consumables from Gyrus. Indeed, this quid pro quo of the purchase of consumables was a tacit condition of the gifting of free equipment and or improper bundling and discounting of equipment and consumables.

100. Examples of these consumables include cutting forceps and biopsy forceps.

101. Further, Gyrus sales representatives received stipends of up to $2,300 per month. Gyrus did not require its representatives to maintain any records of their stipend expenditures. Gyrus intended that these stipends be used to entertain physicians, in particular "KOLs" ("Key Opinion Leaders") and "VIPs" ("Very Important Persons"), in exchange for business. Hence the company intentionally sought to conceal these unlawful *quid pro quos* by eliminating record keeping requirements.

102. In addition to the monthly stipend, Gyrus sales representatives and marketing personnel were permitted to submit expense reports for reimbursement for physician-

entertainment expenses. The record keeping "requirements" for these reports were extremely lax.

103. For example, during Relator's review of Gyrus expense reports, he identified multiple instances where the sole documentation of purported dinner expenses in the amount of $200 or more was the tear away portion of a restaurant check.

104. Gyrus also paid tens of thousands of dollars and sometimes more than $100,000.00 per year to individual physicians as compensation for speaking engagements. Oftentimes there was no written contract for speaking services in place and amounts paid to speakers was based exclusively on sales potential without regard for the fair market value of the speaking services. Where a written contract was in place, it was loosely interpreted to favor the physician financially. Gyrus instituted this sham speaker program to meet one goal - to induce sales to key accounts and to falsely promote products. In many cases, speaker fees were also paid in exchange for promoting Gyrus products off-label.

105. Relator estimates that Gyrus is giving away millions of dollars of equipment pursuant to this kickback arrangement.

106. All claims tainted by kickbacks provided by Gyrus constitute false claims as that term is defined by the FCA. By providing these kickbacks, Gyrus has caused these false claims to be submitted to Medicare and other government-funded healthcare programs.

E. "Permanent Loans" and Give-Aways of Medical Equipment

107. Olympus routinely provides kickbacks to hospitals, physicians and physician practices in the form of free products or the free use of equipment, disguised in the form of discounts or equipment loans.

108. None of the free gifts comply with the Medicare anti-kickback safe harbor for legitimate discounts.

109. Olympus sales representatives routinely gave medical equipment to hospitals and physicians under the category of a "permanent loan" and/or "MLS - Medical Loaner Scope." In other words, there was no loan; this equipment was given as a gift. Many times clients were also provided with a highly valuable service maintenance agreement at no charge, to provide additional financial incentive.

110. The purpose of these permanent loans and long term loans was to gain market share at inflated prices, as well as to induce hospitals and physicians to purchase additional equipment, supplies, and/or consumables from Olympus and/or later, from Gyrus.

111. The Olympus practice was to give the equipment to "KOLs" and "VIPs" in the market. In other words, the purpose of the give-away is to get the equipment in the hands of the most highly regarded physicians in the marketplace so that these physicians promote Olympus products to other physicians and hospitals and so that KOLs influence the hospitals with which they affiliate to purchase Olympus products.

112. All claims tainted by kickbacks provided by Olympus constitute false claims as that term is defined by the FCA. By providing these kickbacks, Olympus has caused these false claims to be submitted to Medicare and other government-funded healthcare programs.

113. Olympus routinely provides hospitals with free products of both capital equipment including scopes, imaging products and generators and consumables and disposables such as forceps and sheaths. The capital equipment costs approximately $15,000.00 to $30,000.00 and is used in conjunction with the various consumable and disposable products.

These gifts were given in exchange for the hospital's agreement to buy Defendants' consumable products, and also to give Defendants' products preferred status.

114. Various circumstances arose which caused Olympus sales representatives to "permanently" "loan" medical equipment to a hospital with no intention of ever receiving compensation for it.

115. In one such situation in 2002, an Olympus sales representative delivered his personal demo endoscopes to Winter Haven Hospital. This was 8-10 endoscopes with at least 7 scopes left in the G.I. lab *permanently*. The approximate value of the Olympus equipment on "loan" to the hospital *at no charge* is $175,000.00-$200,000.00.

116. Olympus also used these "permanent loans" as part of its effort to prevent its customers from switching to a competitor. An Olympus Regional Sales Director stated in an email that the equipment had to be kept on site at a University of Illinois Medical Center in order "to prevent a conversion away from Olympus to" a competitor.

117. Sometimes, sales representatives gave away the medical equipment as a "promotion" or as a "demo unit," or as part of its "customer relations."

118. In 2009, an Area Vice President requested that certain equipment be given to Barnes Jewish Hospital in St. Louis in an effort to "correct past mistakes and get a fresh start," because he acknowledged that "*[t]oday* leaving them with her as permanent loaners would be *illegal*." The Area VP acknowledged this notwithstanding the hospital's statement that "Olympus 'Bob" *promised* the above items would be left at her facility on permanent loan…"

119. In another instance, an Olympus sales representative gave a customer (Endo Red Bank - NJ) a $35,000 video processor for free if it purchased 4 new scopes. However, emails reflect that the customer never even purchased the 4 new scopes.

120. Olympus' standard procedure for sales representatives who wished to "loan" equipment to their customers involved the sales representative filling out a "Service Agreement Exception Request Form."

121. On this form, the sales representative listed the pertinent information such as the customer (physician or hospital), the date, the address, the number of scopes on contract, and then the representative had to describe the "background and supporting justification" for "loaning" out the equipment.

122. For one particular loan request in June, 2009, the representative stated that "Dr. Basu [5 Station Square, Forest Hills, NY 11375] will sign a Fee For Service Agreement with 6 scopes. He was promised a set of on-site loaners if he converted his Pentax equipment to Olympus." Pentax is one of Olympus' major competitors.

123. On this same "Service Agreement Exception Request Form" it states the "Standard Policy":

> The customer must have a minimum of six (6) GI Video Endoscopes covered by the Service Agreement to be eligible for on-site back-up scopes. One (1) set of Back-up scopes (GIF/CF) is provided to accounts with 6 to 23 GI Scopes and Two (2) sets are provided to accounts with 24+ GI Scopes covered by the Service Agreement. Service coverage is included for all on-site scopes. FULL SERVICE customers are provided back-up scopes that are one generation back from their current inventory based on a simple majority of contact scopes (i.e., six 160s and five 140s = 140 series on-site back-up). VALUE SERVICE customers are eligible for two generations back on-site scopes with an option, based on availability and for a fee, to upgrade to one generation back instruments.

124. Thus, Olympus' "standard policy" is to provide its customers with free equipment in exchange for the customer buying a targeted volume of Olympus' products.

125. By receiving free products, hospitals reduce costs and increase reimbursement on each procedure performed with the Olympus free products.

126. All claims tainted by kickbacks provided by Olympus as described in this subsection, and in the subsections *infra*, constitute false claims as that term is defined by the FCA. By providing these kickbacks, Olympus has caused these false claims to be submitted to Medicare and other government-funded healthcare programs.

F. Leasing Programs

127. In addition to its "permanent loans" of medical equipment, Olympus also "leased" equipment to customers.

128. In reality, the lease program is essentially a "debt forgiveness" program because the lease transactions facilitate Olympus' giving medical equipment away for free.

129. Olympus' routine sales practice is to lease medical equipment to its customers, and then allow the customer to keep the equipment if they enter into a new "lease."

130. Similarly, in an effort to increase sales of its medical equipment and not lose customers, Olympus forgave, or "wrote off" hundreds of thousands of dollars in unpaid debt from its customers.

G. Grants

131. From approximately 2000 until approximately 2009, when Relator attempted to change the way Olympus conducted its grant program, grants were determined and given away exclusively by the Olympus sales and marketing personnel.

132. It was commonly known at Olympus that the giving of grants was directly tied to sales potential. To ensure grants were based on sales potential, the principal decision makers appointed to sit on the grant committee prior to 2009 were sales and marketing executives and customer development personnel, including John Temple, Rick Harbuck, Eric Halverson, Bob Rheinhardt, Frank Fillciotto, and Yukio Nakajima.

133. Approved by management, sales and marketing personnel gave hundreds of thousands of dollars in "grants" to physicians and medical facilities ostensibly for an educational program or research program. The grants have actually been used to provide kickbacks to physicians and companies to do whatever they wanted with the money, in return for business.

134. By way of example, on October 27, 2009, there was a meeting among the CEO of Olympus (Mark Gumz), the Vice President of All Medical Products (Rick Harbuck), the Vice President of Sales West Coast Dennis Sporleder, and Dr. Inderbir Gill of USC Medical Center to discuss the possibility of Olympus giving Dr. Gill and USC a grant.

135. The minutes of this meeting reflect Dr. Gill's statement that Olympus is the type of organization that USC is looking to "create a business partnership with."

136. Dr. Gill also discussed his plans "on creating the first NOTES Fellowship in LESS[,]" an off-label use of the Olympus medical devices.

137. Dr. Gill concluded the meeting by stating that he was looking forward to "entering into a partnership" with Olympus.

138. By the time this meeting took place, Relator had reconstituted the grant process such that Gumz, Harbuck, and Sporleder should have advised Dr. Gill to submit a grant application. Instead, the most Senior Olympus America marketing executives entertained Dr. Gill's oral solicitation of a grant, in an apparent attempt to subvert Relator's attempts to bring Olympus's grant protocols into compliance.

139. Following the meeting, Kenney Harada[4] sent an email to Mr. Harbuck stating that, "we would like to understand OAI's stance to support Dr. Gil [sic]... (USC) for the future business expansion (any future sales potential?)".

[4] Of note, Kenney Harada was the Chief Manager, Europe and Americas Sales Marketing and he was based in Tokyo, Japan. The fact that the Olympus America marketing executives communicated Dr.

140. When Relator saw the meeting minutes and the email from Mr. Harada, he verbally questioned Gumz about the impropriety of this type of discussion surrounding a grant.

141. In response to Relator's questioning, Gumz then deleted these documents from his computer, which Relator witnessed.

142. Relator reviewed the minutes of several Grant Committee meetings that predated his appointment as Compliance Officer. The meeting minutes corroborate Relator's claims regarding Olympus's abuse of the grant process to gain favor with VIPs and KOLs for the purpose of generating sales.

143. In or about late 2011 or early 2012, Olympus briefly suspended the operations of the grant committee. Upon information and belief, Olympus took this drastic step due to compliance concerns.

144. As of October 2012, Olympus had once again suspended the grant program for grants seeking funding for the following: independent medical research grants, fellowship grants, or charitable donations, including permanent equipment donations.

H. Olympus' Misuse of Honorarium, Speaker Fees or Consulting Fees for Physician Marketing

145. From approximately 2000 through 2009 when Relator revamped the program, Olympus had no policy for paying physicians for speaking engagements.

146. This was left to the discretion of Olympus sales representatives, with the approval of Olympus management.

147. When a physician was asked to speak, the physician typically did not sign a speaker engagement agreement.

Gill's grant solicitation to a senior executive in Japan, who promptly injected himself into the discussion by asking whether Dr. Gill presented future sales potential is yet further evidence of Olympus' executives intent to subvert Relator's compliance efforts.

148. Until Relator overhauled the program in 2009, Olympus paid the physicians whatever amount they demanded, often up to $100,000.00 per year.

149. Approved by management, Olympus paid physicians hundreds of thousands of dollars per year, which was ostensibly compensation to physicians for agreeing to speak at a formal speaking engagement. In reality, Olympus was paying these physicians for using Olympus products and to promote use of Olympus products to colleagues with influence over medical device and equipment purchasing decisions.

150. Olympus engaged in a similar practice with physician consulting payments which were far in excess of the fair market value of any consulting work performed, if any.

151. The following physicians received speaker fees and/or consulting fees during Relator's employment with Olympus: Dr. Charles Lightdale, Dr. King, Dr. Curlillo, Dr. Petrini and Dr. Preminger from Durham, North Carolina.

I. Gyrus also Operated without Formal Agreements

152. Like Olympus, Gyrus, also operated without formal consulting agreements with its physicians and/or customers.

153. Upon information and belief, until approximately 2009, it was common practice at Gyrus for sales representatives to enter into informal arrangements with physicians and hospitals for various things, including without limitation, speaking engagements and consulting services.

154. This was done with management approval.

155. Dr. Thomas Lyons, Dr. Charles Koh, Dr. Deborah Wilson, Dr. Francois Bladeau and Dr. Pranikoff were a Gyrus VIPs/KOLs who received consulting and/or speaker fees from Olympus/Gyrus.

J. Olympus Treats Physicians to Luxury Vacations

156. Olympus routinely treated various physicians to expensive trips to exotic locations.

157. For example, Olympus would pay physicians to travel to Japan, all expenses paid, where they would stay at lavish hotels, eat expensive meals, and be entertained, all on the company dime.

158. Physicians who enjoyed these trips to Japan and other international vacation destinations included Dr. Charles Lightdale, Dr. Peter Cotton, Dr. Grace Elta and Dr. Michael Sivik.

159. Up until approximately 2008, Olympus America executive Hiroshi Ichikawa masterminded, implemented and endorsed the physician entertainment scheme. The most senior Olympus America executives, including Gumz, were aware of and supported these activities. Yukio Nakajima assumed this role after Ichikawa stepped down and he is actively involved in physician entertainment activities at the present time.

160. Pursuant to Olympus's formal job description for the position of Director, Customer and Business relations, Nakajima's "essential duties and responsibilities" admittedly include "organizing and arranging visits of physicians to Olympus Tokyo…."

161. Olympus also sponsored physician vacations disguised as physician education. For example, Olympus sponsored an annual event called the Masters MIS forum. In 2009, the forum was held at the prestigious Colony Hotel in Kennebunkport, Maine on July 7-11.

162. Prior to 2009, this was an all expense paid trip for approximately 50 handpicked VIP and KOL Olympus physician customers.

163. Dr. David Ratner, an Olympus VIP himself, organized the event on behalf of Olympus.

164. Beginning in 2009, as soon as he discovered the boundless - and unlawful - nature of Olympus's benevolence towards key customers through this event, Relator imposed strict limitations on the physician expenses paid for by Olympus.

165. He also required that every physician who sought Olympus funding to attend the event enter into a written consulting agreement, in an effort to limit and to legitimize the reimbursement process.

166. Olympus's lavish entertaining of physicians extended beyond VIPs and KOLs in the United States. Relator discovered upon his assuming his compliance position that Olympus routinely wined and dined physicians and funded expensive trips for physicians who practiced in foreign countries and regions, including Canada, Mexico and Latin America. These physicians predominately meet the FCPA's broad definition of "foreign official," because healthcare is publicly-funded in those countries and regions.

167. For example, Olympus regularly treated Canadian physicians to extravagant California vacations that Olympus sought to disguise as business trips to Olympus's San Jose repair facility. While the physicians may have visited the facility briefly, the vast majority of the trip was spent touring Northern California cities such as San Francisco, dining at expensive restaurants and participating in various sporting and entertainment activities, such as golf. The brief visits to Olympus' repair facility did not shroud these extravagant trips with a legitimate business purpose.

168. Relator was stunned not only by the pervasive lack of education and compliance with the FCPA, but the push back from his colleagues when he attempted to cease Olympus's unlawful conduct.

169. For example, Relator had multiple interactions about FCPA compliance with Bill Collins, who held the position of Group Vice President of the Medical Services Group for Olympus Canada. Collins fiercely resisted Relator's efforts to reform Olympus's business practices in Canada.

170. For example, in one email communication with Relator on October 7, 2009, Collins complained that "not all companies in Canada are following the FCPA," and despite claiming he was not trying to "lobby" for non-compliance of the FCPA, he complained, "we are at a market disadvantage compared to our competitors."

171. To prove his point, Collins attached to the email an invitation to a lavish party for physicians and nurses sponsored by Boston Scientifics. Collins's complaint arose because Relator had prohibited Collins from organizing similar parties, meals and give-aways for Olympus Canada physician-customers and nurses.

172. In December 2009, not long after the email exchange with Collins, Relator was scheduled to give a FCPA compliance training seminar at Olympus Canada headquarters. The trip was cancelled at the last minute.

173. Relator was not deterred by corporate resistance to his compliance efforts. For example, as is set forth above, developing and implementing policies and procedures for compliance with this statute was a core component of the Compliance Officer position. Accordingly, Relator drafted a memorandum dated February 25, 2010 that provided an overview of the FCPA along with examples of "dos" and "don'ts."

174. Relator arranged for the memorandum to be included in an information packet distributed to Olympus employees, including Olympus sales representatives employed outside the United States, who were attending a major trade show. Relator was immediately retaliated against for disseminating the memorandum.

175. Shortly after the tradeshow, Relator was slated to give a presentation on the FCPA to numerous executives and agents from Olympus America and Olympus Latin America at an executive retreat in Miami; however, Gumz summarily cancelled Relator's presentation and removed Relator from the retreat attendee list.

176. Relator's planned presentation for the retreat was of critical importance to his compliance efforts because it presented a rare opportunity for Relator to provide in person FCPA training to Olympus Latin America executives and agents.

177. Merely one (1) month later, Gumz removed Relator from his position as Compliance Officer, as is set forth below.

K. Relator's Attempts to Cure Defendants' Compliance Issues

178. During the course of his employment with Olympus, Relator diligently sought to ensure that Olympus sales and marketing representatives complied with the numerous compliance rules and regulations applicable to the industry.

179. In February of 2009, Relator quickly prepared plans for an Olympus Compliance department. These plans included covering areas of risk, priorities, organization and administration; however, Relator's efforts were thwarted at every turn.

180. In fact, from February 2009 through March 2010, Gumz consistently rebuffed Relator when he raised compliance issues.

181. Relator was essentially stripped of all decision-making ability and was told just to be the Chief Compliance Officer. Since Relator was divested of authority to enforce compliance with federal laws including the False Claims Act and Anti-kickback statute, his sole recourse was to report violations of such laws with the Olympus Ethics department. Not surprisingly, Relator's complaints fell on deaf ears and Olympus's unlawful conduct continued unabated.

182. Gumz further intentionally restricted Relator's compliance efforts by preventing him from hiring staff to implement a full compliance program.

183. Relator verbally questioned offers of free medical equipment made to customers of Olympus and objected to practices of Defendants' sales and marketing representatives when he believed applicable standards, guidelines and statutory obligations were not being followed.

184. CEO Mark Gumz stated to Relator that he wanted Relator in the compliance role to try to figure out how to "work around the rules" so as to "not impact the business."

185. During the course of Relator's almost twenty-year employment with Olympus, Relator observed repeated and continuous efforts by Olympus to use research incentives as a means to persuade physicians to use Olympus products, to increase Olympus sales, and to increase market share.

186. Moreover, Relator also questioned the management-approved practice of Olympus sales representatives routinely entertaining physicians with lavish meals, golf and trips to exotic locations.

187. Accordingly, after witnessing years of repeated compliance problems and offenses by Olympus including those detailed *infra*, Relator initiated a program to attempt to address these issues as soon as he was promoted to Compliance Officer in February 2009.

188. Prior to that time, Olympus never even had a compliance department and Olympus had utterly failed to train its employees about the seminal laws that govern sales and marketing of medical devices and equipment, including the FCA, the AKS and the FCPA. The lack of training on these core subjects is indicative of the unlawful manner in which Olympus was conducting business domestically and internationally.

189. Likewise, Gyrus had no real compliance department when Olympus acquired it, and no real efforts toward compliance were made until Relator stepped in.

190. In or around late 2009, Relator developed a detailed and comprehensive Compliance Program at Olympus, the goal of which was to ensure corporate-wide compliance with all rules and regulations applicable to Olympus.

191. Relator dedicated countless hours compiling spreadsheets, PowerPoint programs, graphs, and charts detailing his vision for the company's compliance program.

192. This initiative was met with resistance from Gumz, who became increasingly paranoid about Relator's efforts in this regard.

193. Gumz's paranoia began to turn personal toward Relator in early 2010.

L. Olympus Retaliates Against Relator

194. In or around late 2009, at the same time Relator was attempting to bring Olympus into full compliance, Olympus CEO Mark Gumz began to ostracize and harass Relator.

195. Prior to this time, Relator and Gumz had enjoyed a close, long-standing relationship in which Gumz had often turned to Relator for business and personal advice.

196. Now, however, Gumz sought to make Relator extremely uncomfortable in his daily work environment.

197. By way of example only, after almost twenty years of employment with Olympus, including an unblemished record, highlighted with increased responsibilities and continuous promotions, on March 30, 2010 Gumz called Relator to address, for the first time, Olympus' alleged concern about Relator's work performance.

198. At this time, Relator received, for the first time in almost twenty years of receiving exemplary performance reviews, a non-standard verbal sub-par performance review based on vague notions of "non-performance." Relator expressed his disagreement with the purported review.

199. Indeed, on March 30, 2010, Relator was removed from the position of Chief Compliance Officer, ostensibly for "performance issues."

200. Relator's removal was entirely baseless. Just months before, in November 2010, Relator had undergone a performance review; his performance was documented as above average.

201. Due to the increasing stress and systematic harassment being inflicted upon Relator, Relator began to experience serious health concerns early in 2010.

202. On March 22, 2010, Relator went out on sick leave under the Family Medical Leave Act.

203. On March 30, 2010, Olympus representatives informed Relator over the telephone that he had been relieved of his compliance responsibilities.

204. On March 30, 2010, Olympus sent around a written statement that a new "acting" compliance officer had been named.

205. Relator continued on disability leave for several months.

206. Olympus terminated Relator's employment effective September 8, 2010.

207. There can be no dispute that Relator consistently put Olympus top executives including Gumz on notice of it violations of the False Claims in an attempt to put an end to Olympus' fraud on the government. The last of many conversations on this subject with Olympus executives occurred immediately prior to Relator taking medical leave.

208. Specifically, on March 18, 2010, Relator discussed these issues with President and Chief Executive Officer, Olympus Corporation of the Americas, Mark Gumz, over lunch. Gumz replied that he did not want to hear about it, and that he put Relator in the position of Compliance Officer intending for him to "work around" the laws.

209. On one specific occasion, Relator spoke to Gumz regarding a compliance issue that involved Gumz directly. Specifically, Relator brought to Gumz's attention notes of a meeting attended by Gumz, sales executives, and customers that memorialized inappropriate discussions concerning grants and off-label sales. Gumz took exception to Relator's comment, but promptly went to his computer and deleted the meeting notes from his email, announcing words to the effect that "no one will find it now." Gumz then instructed Relator to hand over his copy and to make sure no other copies of those notes exist; however, Relator kept a copy. The subject of that meeting, as well as the meeting notes themselves, are discussed in detail, *supra.*

210. Olympus's retaliation against and termination of Relator parallels the experience of Olympus Corp's former President and CEO Michael Woodford. Woodford was terminated on October 14, 2011, just two weeks after being appointed as CEO. In a public statement, Olympus attempted to blame the ousting on a "clash in management style with other senior executives." It was subsequently revealed, however, that this "clash" was Woodford's refusal to perpetuate and cover up Olympus's fraudulent business practices.

211. Just like Woodford, when Relator's efforts to make the company complaint with the AKS, the FCA and the FCPA, among other laws, "clashed" with the Olympus America's executive management's way of doing business, he was summarily removed from his role as Compliance Officer and ultimately forced out of the company.

212. Interestingly, in or about August 2012, Olympus Corp's Chairman Yasuyuiki Kimoto revealed during an interview with a prominent media outlet that Olympus Corp had "voluntarily" reported possible violations of the FCPA relating to Olympus's handling of physician travel, meals and/or entertainment expenses at a single training facility in Brazil to the Department of Justice.

213. Relator believes the Chairman's disclosure was a diversionary tactic calculated to divert enforcement efforts away from the company's prolific FCA and AKS violations.

214. Indeed, Olympus's unlawful expenditures on physicians in foreign countries mirrors its treatment of physicians here, where Olympus America sales representatives have been permitted and encouraged at an executive level to lavish trips, meals and other activities upon physicians to generate sales and market share. This conduct is endemic to Japanese culture, and all Olympus corporations were managed in accord with this culture.

CLAIMS FOR RELIEF

COUNT I

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(A) [5] Presenting or Causing to be Presented False Claims

[5] On or about May 20, 2009, Congress amended and renumbered the Federal False Claims Act pursuant to the Fraud Enforcement and Recovery Act ("FERA"), Pub.L.No. 111-21, §4, 123 Stat. 1617, 1621 (2009). 31 U.S.C. §3729(a)(1)(A) was previously numbered 31 U.S.C. §3729(a)(1). Relator avers the FERA amendments are retroactive and apply to all false claims submissions complained of herein, but to the extent that the FERA amendments are deemed not to be retroactive, this Count should be deemed to include violations of the FCA prior to the FERA amendments, specifically, 31 U.S.C. §3729(a)(1).

215. Relator and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

216. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729 *et seq.*

217. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A) provides:

> "Liability for certain acts. Any person who--
>
> (A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval … ."

Id.

218. By virtue of the above-described acts, among others, since at least 2000, Defendant Olympus knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 31 U.S.C. § 3729(a)(1)(A).

219. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is an express condition of eligibility and payment of a claims submission for reimbursement under the Medicare program.

220. In other words, when a claim presented to Medicare arises from conduct which violates the Anti-Kickback Statute are, as a matter of law, that claim is ineligible for

reimbursement, and upon submission, is a false claim subject to the provisions of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

221. By engaging in the fraudulent and illegal practices described herein, including but not limited to the provision of free medical equipment to physicians and hospitals, and in kind payments to doctors in the form of honoraria and lavish trips, among other things, Defendants violated the Anti-Kickback Statute.

222. Defendants' material violations of the Anti-Kickback Statute led to the presentation to Medicare of claims for patients unlawfully referred by physicians who were offered and accepted such kickbacks. Every claim submitted to the United States for services rendered to a patient unlawfully referred was false, as they were ineligible for reimbursement, and therefore by submitting or causing these false claims to be submitted, Defendants further violated 31 U.S.C. §3729(a)(1)(A) from at least 2000 through the present.

223. Defendants also caused the submission of false claims for off-label use of defendants' products, as detailed *supra*.

224. Relator United States, unaware of the falsity of the claims that Defendants caused doctors and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid Defendants, doctors and other health care providers for claims that would otherwise not have been allowed.

225. For those claims that Defendants submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to this Action, Defendants acted with the requisite scienter.

226. The amounts of the false or fraudulent claims to the United States were material. Relator United States, being unaware of the falsity of the claims and/or statements caused to be

made by Defendants, and in reliance on the accuracy thereof paid and continues to pay false claims for medical equipment and for procedures conducted with that equipment.

227. It is believed that as a result of Defendants' violations of 31 U.S.C. § 3729 (a)(1)(A), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

COUNT II

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(B)[6]

Creation or Use of False Statements or Records Material to a False Claim

228. Relator and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

229. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729 *et seq.*

230. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B) provides:

"Liability for certain acts. Any person who--

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

Id.

[6] On or about May 20, 2009, Congress amended and renumbered the Federal False Claims Act pursuant to the Fraud Enforcement and Recovery Act ("FERA"), Pub.L.No. 111-21, §4, 123 Stat. 1617, 1621 (2009). 31 U.S.C. §3729(a)(1)(B) was previously numbered 31 U.S.C. §3729(a)(2). Relator avers the FERA amendments are retroactive and apply to all false claims submissions complained of herein, but to the extent that the FERA amendments are deemed not to be retroactive, this Count should be deemed to include violations of the FCA prior to the FERA amendments, specifically, 31 U.S.C. §3729(a)(2).Relator

231. By virtue of the above-described acts, among others, Defendants knowingly made used or caused to be made or used false records or statements material to false or fraudulent claims paid by the United States, and possibly continues to do so, in violation of 31 U.S.C. § 3729(a)(1)(B).

232. For example, claims for reimbursement would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Action, including its false records and statements.

233. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs. The claims Defendants submitted or caused to be submitted failed to disclose the underlying violation of the Anti-Kickback Statute and/or affirmatively misrepresented that the clams were made in compliance with all applicable laws including the Anti-Kickback Statute.

234. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute. Defendants' material violations of the Anti-Kickback Statute led to the submission of claims for to the United States.

235. Those claims were false, as they were ineligible for reimbursement, and by making or causing to be made false records or statements material to the false claims, Defendant Olympus further violated 31 U.S.C. § 3729(a)(1)(B) from at least 2000 to 2009.

236. The records of statements made or used, or caused to be made or used, by Defendants were material to the false claims submitted to the United States government.

237. Relator United States, unaware of the falsity of the records and/or statements which the Defendants made or used, or caused doctors and other health care providers to make, and in reliance on the accuracy thereof, paid Defendant Olympus, doctors and other health care providers for claims that would otherwise not have been allowed.

238. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims.

239. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

240. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants' false records and statements made or used or caused to be made or used to the United States were material.

241. As a result of Defendants' violations of 31 U.S.C. § 3729 (a)(1)(B), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

COUNT III
Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(G)[7]

[7] On or about May 20, 2009, Congress amended and renumbered the Federal False Claims Act pursuant to the Fraud Enforcement and Recovery Act ("FERA"), Pub.L.No. 111-21, §4, 123 Stat. 1617, 1621 (2009). 31 U.S.C. §3729(a)(1)(G) was previously numbered 31 U.S.C. §3729(a)(7). Relator avers the FERA amendments are retroactive and apply to all false claims submissions complained of herein, but to the extent that the FERA amendments are deemed not to be retroactive, this Count should be deemed to include violations of the FCA prior to the FERA amendments, specifically, 31 U.S.C. §3729(a)(7).

Making, Using or Causing to be Made or Used, a False Record or Statement Material to an Obligation to pay or Transmit Money or Property to the United States or Concealing, Improperly Avoiding or Decreasing an Obligation to Pay or Transmit Money or Property to the United States

242. Relator and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

243. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730, for Defendants' violations of 31 U.S.C. § 3729 *et seq.*

244. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G) provides:

"Liability for certain acts. Any person who--

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

Id. The term "obligation" means:

> "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, form a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment..."

31 U.S.C. § 3729(b)(3).

245. By virtue of the above-described acts, among others, Defendants knowingly made, used, or caused to be made or used false records or statements, and possibly continue to do so, in violation of 31 U.S.C. § 3729(a)(1)(G).

246. Relator informed Defendants of the various compliance problems, but they never took the required and appropriate steps to satisfy the obligation owed to the United States, refund or return such overpayments, or to inform Medicare of the overbilling, and instead continued to

retain the same. It is unclear whether Olympus is compliant with its regulatory obligations at the present time since Relator is not presently at the company.

247. As a result of Defendants' violations of 31 U.S.C. § 3729 (a)(1)(G), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

COUNT IV

California False Claims Act
Cal Govt Code §12651(a)(1)-(3)

248. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

249. This is a claim for treble damages and penalties under the California False Claims Act.

250. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

251. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

252. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

253. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

254. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT V

Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1)-(3)

255. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

257. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

258. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

259. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

260. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

261. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT VI

Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

262. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

264. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

265. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

266. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

267. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

268. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT VII

Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

269. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

271. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

272. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

273. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

274. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

275. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT VIII

Illinois False Claims Act,
740 Ill. Comp. Stat. §175/1 *et seq.*, as amended 2010

276. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

278. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

279. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

280. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

281. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

282. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT IX

Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1)-(3)

283. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

284. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

285. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

286. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

287. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

288. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

289. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT X

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

290. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

291. This is a claim for treble damages and penalties under the Nevada False Claims Act.

292. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

293. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

294. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

295. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

296. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XI

New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 et seq. and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 et seq

297. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

298. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

299. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

300. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

301. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

302. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

303. The State of New Mexico is entitled to civil penalties for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XII

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

304. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

306. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

307. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

308. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

309. By reason of the defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

310. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XIII

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

311. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

313. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

314. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

315. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

316. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

317. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XIV

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

318. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

319. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

320. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

321. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

322. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

323. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

324. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XV

Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1)-(3)

325. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

327. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

328. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

329. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

330. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

331. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XVI

District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14 (a)(1)-(3), (7)

332. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

333. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

334. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

335. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

336. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

337. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

338. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XVII

Georgia False Medicaid Claims Act
O.C.G.A. §§ 49-4-168 et seq.

339. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

341. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

342. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

343. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

344. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

345. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XVIII

Indiana False Claims and Whistleblower Protection Act
I.C. 5-11-5.5

346. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

348. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

349. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

350. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

351. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

352. The State of Indiana is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XIX

Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et. seq

353. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

354. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

355. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

356. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

357. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

358. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

359. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XX

Michigan Medicaid False Claims Act
MCL 400.601-400.613

360. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

362. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

363. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

364. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

365. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

366. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXI

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

367. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

369. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

370. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

371. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

372. By reason of the defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

373. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXIII

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

374. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

376. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

377. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

378. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

379. By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

380. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXIII

Oklahoma Medicaid False Claims Act
2007 OK. ALS 137

381. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

383. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

384. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

385. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

386. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

387. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXIV

New Jersey False Claims Act
N.J. Stat. § 2A: 32C-1 et seq.

388. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

390. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

391. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

392. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

393. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

394. The State of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXV

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

395. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

397. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

398. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

399. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

400. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

401. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXVI

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

402. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

404. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

405. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

406. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

407. By reason of the defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

408. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXVII

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

409. Relator incorporates by reference and realleges all of the foregoing paragraphs as if fully set forth herein.

410. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*

411. The Montana False Claims Act, Mont. Code Ann., § 17-8-403 provides for liability for *inter alia* any person who engages in any or all of the following conduct.

(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

412. By virtue of the conduct alleged herein, including the submissions of non-reimbursable claims described above and the off-label marketing scheme described above, Defendants knowingly violated each of the above subsections of the Montana False Claims Act by and through their intentional and/or knowing violations of federal and state laws, as described herein.

413. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

414. By reason of these improper payments, the Montana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

415. Relator is a private person with direct and independent knowledge of the allegations in this Action, who has brought this action pursuant to the Montana False Claims Act on behalf of himself and the State of Montana.

416. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

COUNT XXVIII

Connecticut Medicaid False Claims Act CHAPTER 319v Sec. 17b-301a et seq.

417. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

418. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act CHAPTER 319v Sec. 17b-301a et seq.

419. By virtue of the acts described above, defendants knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of Social Services.

420. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the payment or approval by the State of Connecticut false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

421. By virtue of the acts described above, defendants conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a

false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

422. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

423. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

424. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXVIV

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

425. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

426. This is a claim for treble damages and penalties under the Minnesota False Claims Act, Minn, Stat, §15C.01 *et seq.*

427. By virtue of the acts described above, defendants knowingly presented or caused to be presented, to an officer or employee of the State of Minnesota and/or political subdivisions, false or fraudulent claims for payment or approval.

428. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false

or fraudulent claims paid ort approved by the State of Minnesota and/or its political subdivisions.

429. By virtue of the acts described above, defendants knowingly conspired to either: 1) present a false or fraudulent claim to the State of Minnesota or a political subdivision for payment or approval; or, 2) makes, use, or cause to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim

430. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

431. By reason of the defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

432. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXX

Maryland False Health Claims Act of 2010

Subtitle 6, False Claims Against State Health Plans and State Health Programs, §2-601 *et seq.*

433. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

434. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

435. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

436. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

437. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal business practices.

438. By reason of the defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

439. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XXXI
Colorado Medicaid False Claims Act
C.R.S. § 25.5-4-304 *et seq.*

440. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

441. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 *et seq.*

442. The Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 *et seq.* provides for liability for *inter alia* any person who engages in any or all of the following conduct.

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

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

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

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

...

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

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

443. By virtue of the conduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above, Defendants knowingly violated each of the above subsections of the Colorado Medicaid False Claims Act by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, as described herein.

444. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

445. By reason of these improper payments, the Colorado Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT XXXII
Iowa Medicaid False Claims Act
Iowa Code Ann. §685.1 *et seq.*

446. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

447. This is a claim for treble damages and penalties against all Defendants on behalf of the State of Iowa under the Iowa Medicaid False Claims Act, Iowa Code §685.1 *et seq.*

448. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the State of Iowa.

449. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Iowa to approve and pay such false and fraudulent claims.

450. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

451. By reason of the Defendants' unlawful acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

452. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants plus treble damages.

COUNT XXXIII
Washington Medicaid Fraud False Claims Act
West's RCWA 43.131.0001 *et seq.*

453. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

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

455. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

456. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

457. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

458. By reason of the Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

459. The State of Washington is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

PRAYER

WHEREFORE, Relator acting on his own behalf, on behalf of the United States and on behalf of the Relator States respectfully demands and prays that this Court enter judgment against Defendants as follows:

1. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of defendants' actions, plus the maximum civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, C.R.S. §25.5-4-304, et seq.;

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus the maximum civil penalty of $10,000 for each violation of CHAPTER 319v Sec. 17b-301a et seq.;

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082;

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of the Illinois False Claims Act, 740 Ill. Comp. Stat. §175/1 et seq., as amended 2010;

9. that this court enter judgment in Relators' favor and against defendants in an amount equal to three times the amount of damages Iowa has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Iowa Medicaid False Claims Act;

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Maryland False Health Claims Act of 2010, Subtitle 6, False Claims Against State Health Plans and State Health Programs, §2-601 *et seq.*;

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of defendants' actions, plus the maximum civil penalty of $11,000 for each violation of Minn. Stat. § 15C.01 *et seq*;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14-1 et seq. and N.M. Stat. Ann. §44-9-1 et seq;

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605 et seq.;

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5-182(a);

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of

defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a);

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 et seq;

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus civil penalties for each violation of I.C. §5-11-5.5;

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 et seq.;

24. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

25. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 et seq.;

26. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137;

27. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 et seq.;

28. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 et seq.;

29. that this Court enter judgment against defendants in an amount equal to three times the amount of damages Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. §20.931 et seq.;

30. that this Court enter judgment against defendants in an amount equal to three times the amount of damages Montana has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*;

31. that this court enter judgment in Relator's favor and against defendants in an amount equal to three times the amount of damages Iowa has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Iowa Medicaid False Claims Act;

32. that this Court enter judgment against defendants in an amount equal to three times the amount of damages Washington has sustained because of the defendants' actions, plus a civil penalty of $11,000 for each violation of the Washington Medicaid False Claims Act;

33. that Relator be awarded the maximum amount allowed as a Relator's Share pursuant to §3730(d) of the federal False Claims Act and the equivalent provisions of the state statutes set forth above;

34. that Relator be awarded all costs of this action, including attorneys' fees and expenses pursuant to §3730(d); and,

35. that Relator recover such other relief as the Court deems just and proper, or that is necessary to make Relator whole.

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TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

Respectfully Submitted,

KENNEY & McCAFFERTY, P.C.

BY: _____

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ATTORNEYS FOR RELATOR

Dated: February 4, 2016