THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA *EX REL.* JAMES MARCHESE,

Plaintiff,

v.

CELL THERAPEUTICS, INC., MEDCOMM SOLUTIONS, ENVISION PHARMA, INC., and AMERISOURCEBERGEN CORP.

Defendants.

No. 06-0168 MJP

PLAINTIFF'S CORRECTED FIRST AMENDED COMPLAINT

JURY DEMAND

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On behalf of the United States of America and pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 (2005) (the "FCA"), Plaintiff and Relator James Marchese ("Relator"), files this *qui tam* Amended Complaint against Defendants CELL THERAPEUTICS, INC. ("CTI"), MEDCOMM SOLUTIONS ("MedComm"), ENVISION PHARMA, INC. ("Envision"), and AMERISOURCEBERGEN CORP. ("AmerisourceBergen") (collectively "Defendants"). Relator alleges as follows:

I. INTRODUCTION

1. Relator brings this *qui tam* action to halt the serious patient harm caused by Defendants' unlawful promotion of their prescription medication Trisenox (generic name arsenic trioxide)—including off-label marketing, improper payments to physicians, and failure to disclose side-effects - and to recover for false claims that were caused to be submitted by this scheme.

2. Trisenox is approved by the United States Food and Drug Administration ("FDA") as a treatment for a very rare form of cancer called acute promyelocytic leukemia ("APL"). Trisenox is indicated *only* for the treatment of the 20-30% of APL patients who have relapsed from the standard first-line APL treatment: retinoid and anthracycline chemotherapy. Trisenox is not FDA-approved to treat any other forms of cancer. Because APL is so rare - in the United States only approximately 1,000 patients are diagnosed with the disease each year - and because Trisenox is indicated only to treat the 200 to 300 patients who relapse after treatment with retinoid and anthracycline chemotherapy, Trisenox's sales for its FDA-approved indication are necessarily very limited.

3. To increase Trisenox's sales, Defendants have pursued an illegal off-label marketing and reimbursement scheme in direct contravention of FDA rules and regulations.

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Defendants' unlawful campaign is especially egregious because Trisenox - a form of arsenic - is a powerful drug with difficult-to-detect but serious side-effects.

4. Approximately 25% of relapsed APL patients treated with Trisenox experience APL differentiation syndrome ("APLDS"). APLDS may produce fever, difficulty breathing, lung problems, heart problems, fluid retention and weight gain, and is often fatal if not treated. For most patients, APLDS is treated relatively easily with high doses of steroids. Obviously, early detection of APLDS is critical for successful treatment. The FDA requires a "black box" warning concerning APLDS on the Trisenox label, and Defendants' own materials emphasize the necessity to monitor carefully for APLDS in APL patients because the "signs [of APLDS] are subtle and easy to overlook." CTI knew that symptoms similar to those found in patients with APLDS were occurring in non-APL patients (*i.e.*, in patients who used Trisenox for off-label purposes), but failed to disclose these side-effects to physicians.

5. Relator, a former Oncology Account Manager ("OAM") at CTI and one of CTI's most praised and awarded sales representatives, was terminated from his job after he investigated and documented: (1) Defendants' unlawful off-label promotion of Trisenox; (2) related reimbursement for such off-label use which Defendants knew, or were reckless in not knowing, was illegal; (3) improper kickbacks to prescribing physicians; and (4) side-effects associated with Trisenox, and especially its uses off-label, that Defendants purposefully failed to disclose. Defendants knew or should have known that their unlawful activity would cause physicians, pharmacists, and patients to routinely file false claims for reimbursement from the Government. This is an action to recover damages and civil penalties on behalf of the United States of America pursuant to the *qui tam* provisions of the FCA, based on false claims that were caused

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to be submitted to Medicare and other Government-funded health insurance plans in violation of the FCA.

6. The FCA, 31 U.S.C. § 3729, provides that:

> (a) **Liability for certain acts**. Any person who –
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,[5]00 and not more than $1[1],000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

7. Each of the above FCA subsections provides a specific prohibition against Defendants' conduct involving kickbacks, misrepresentations and causing the submission of non-reimbursable claims to Medicare and other Government-funded health insurance programs.

8. The FCA also protects an employee who has been:

> discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section . . . .

31 U.S.C. § 3730(h).

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Employees who have experienced retaliation are "entitled to all relief necessary to make the employee whole . . . , includ[ing] reinstatement with the same seniority status such employee would have had but for the discrimination, [two] times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." *Id.*

9. Defendants caused false claims to be submitted by:

- improperly marketing Trisenox for off-label uses;
- causing Medicare to reimburse Trisenox prescriptions for off-label uses which reimbursement, Defendants knew, or were reckless in not knowing, was illegal;
- unlawfully promoting Trisenox in violation of the Anti-Kickback Statute and the Stark Law by using thinly-veiled cash payments and other incentives to induce doctors to prescribe Trisenox; and
- failing to disclose Trisenox's dangerous side-effects when used off-label.

Through these prohibited activities, Defendants steered physicians into off-label use and corrupted physicians' independent clinical judgment by failing to provide complete information, and thereby increased the market for Trisenox and caused Trisenox to be reimbursed by the Government when it otherwise would not have been. Had the United States known that such prescriptions were induced by an illegal off-label marketing and reimbursement scheme and by illicit incentives in violation of the Anti-Kickback Statute and the Stark Law, it would not have reimbursed claims for Defendants' drug Trisenox. Defendants thereby caused false claims for payment to be submitted to Medicare and other Government-funded health insurance programs.

10. Relator James Marchese discovered these violations while employed by

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Defendant CTI from October 2000 through September 2002. Relator conducted an investigation and acquired documents demonstrating Defendants' improper conduct and now brings this action on behalf of the United States to recover damages for the false claims that Defendants caused to be submitted.

II. JURISDICTION AND VENUE

11. Relator brings this action on behalf of himself and on behalf of the United States for violations of the FCA. 31 U.S.C. §§ 3729-3733. *See also* The Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 301 *et seq.*; The Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 351 *et seq.*, and 21 U.S.C. § 360aaa *et seq.*; the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq;* and *Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, 21 C.F.R. § 99.1 *et seq.*

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 (conferring federal subject matter jurisdiction) and 31 U.S.C. § 3732 (conferring jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3730 and 3732).

13. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants can be found and/or transact business in this, the Western District of Washington. Additionally, this Court has personal jurisdiction over Defendants because acts prohibited by 31 U.S.C. § 3729 have occurred in this District. 31 U.S.C. § 3732(a). Section 3732(a) authorizes nationwide service of process. *Id.*

14. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants can be found, reside, or transact, or have transacted business in this, the Western District of Washington and/or at least one act proscribed by 31 U.S.C. § 3729 occurred in this District.

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15. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, or in a Government Accountability Office or Auditor General's report, hearing, audit, investigation, or from the news media.

16. To the extent that there has been a public disclosure unknown to Relator, Relator is an original source under 31 U.S.C. § 3730(e)(4). Relator has direct and independent knowledge of the information on which the allegations are based, and has voluntarily provided the information to the Government before filing this *qui tam* action based on that information. *See* 31 U.S.C. § 3730(e)(4).

III. PARTIES

17. Relator JAMES MARCHESE is a resident of the State of New Jersey and a former employee of CTI. Relator held the positions of Oncology Account Manager, with responsibility for field sales in New Jersey and the five boroughs of New York, and Payor Access Manager. The facts averred are based upon Relator's personal observation and documents in his possession. Relator conducted an independent investigation into the wrongdoing by Defendants, acquired relevant documents, and otherwise obtained evidence to support the allegations in this Complaint. Consequently, Relator has direct and independent knowledge of the false statements and/or claims that Defendants, as alleged herein, caused to be submitted to the Government. Relator brings this action on behalf of himself and the United States, pursuant to 31 U.S.C. § 3730(b)(1).

18. Defendant CELL THERAPEUTICS, INC. is a corporation with its principal place of business located at 501 Elliott Avenue West, Seattle, Washington. CTI is principally engaged in the manufacture and sale of pharmaceuticals, including prescription pharmaceuticals subject to

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regulation by the FDA. During all relevant times, Trisenox was CTI's only drug that was FDA-approved for marketing, and Trisenox sales comprised substantially all of CTI's revenue.

19. Defendant MEDCOMM SOLUTIONS has its principal place of business at 1900 Powell Street, Suite 880, Emeryville, California. MedComm is a provider of customized, comprehensive, integrated medical communications, call center, and consulting services to the pharmaceutical, biotechnology and medical device industries. As MedComm's website touts: "[W]e do more than just provide information . . . We Provide Value!" Defendant CTI contracted with MedComm to provide medical information mailings and other support for Trisenox. CTI's sales representatives repeatedly contacted MedComm with reports of Trisenox's side-effects when used off-label, but MedComm failed to warn physicians about these side-effects.

20. Defendant ENVISION PHARMA, INC., is a corporation with its principal place of business located at Southport Crossing, 3530 Post Road, Southport, Connecticut. Envision is a medical and scientific communications company providing commercially focused, strategically driven scientific and technology solutions to the pharmaceutical and biotechnology industries. As Envison's website proclaims: "Our innovative approach provides the right mix of scientific communication services and targeted software applications to augment prescriber awareness and acceptance of compounds at launch and beyond. . . . We partner with our clients to establish long-term relationships that dramatically improve the effectiveness of their product commercialization strategies." Defendant CTI contracted with Envision to assist in organizing and running "Advisory Board" and other promotional meetings concerning, *inter alia*, off-label uses of Trisenox.

21. Defendant AMERISOURCEBERGEN CORP. (NYSE: ABE) is a corporation headquartered in Valley Forge, Pennsylvania. AmerisourceBergen is one of the largest

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pharmaceutical services companies in the United States, servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel by providing, *inter alia*, drug reimbursement consulting services. In or about January 2003 AmerisourceBergen and its subsidiary, AmerisourceBergen Specialty Group, acquired US Bioservices Corporation, including the former Documedics, which had been a division of US Bioservices Corporation since about October 2002. In or about December 2003 the former Documedics was integrated with The Lash Group, an autonomous business unit within the AmerisourceBergen Specialty Group at all relevant times. The Lash Group provides pharmaceutical companies, medical device manufacturers, biotechnology firms, and payers with a broad range of consulting, reimbursement support, and web-based services. Defendant CTI contracted with Documedics to provide reimbursement consulting support for Trisenox beginning in or about January 2001..

IV. DEFENDANTS' UNLAWFUL TRISENOX SCHEME

A. Overview of Relevant Statutes and Regulations

(1) The FCA

22. The FCA provides that any person who "knowingly presents, or causes to be presented, to [the Government] a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," is liable for a civil penalty from $5,500 to $11,000 per false claim, plus three times the amount of damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2).

23. The FCA was substantially amended in 1986 to "enhance the Government's ability to recover losses sustained as a result of fraud against the Government." *See* S. REP. NO. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266. "Congress was acting, in part, in response to judicial decisions taking a restrictive approach to the False Claims Act." *Harrison v.*

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Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999) (citing S. REP. NO. 99-345, at 4, *reprinted in* 1986 U.S.C.C.A.N. at 5269).

24. Given its remedial purposes, the FCA is interpreted broadly, and is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968).

25. The FCA empowers a private person having information regarding a false or fraudulent claim against the Government to bring an action on the Government's behalf and to share in any recovery. 31 U.S.C. § 3730. The complaint must be filed under seal without service on the defendants. *Id*. The complaint remains under seal to give the Government an opportunity to conduct an investigation into the allegations and to determine whether to join the action. *Id*.

26. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States, damages and civil penalties arising from the submission of false or fraudulent claims supported by false or misleading statements that Defendants caused to be submitted to Medicare and other Government-funded health insurance programs for payment by the United States.

(2) FDA Regulation Of Pharmaceuticals: Prohibitions Against Off-Label Marketing

27. The pharmaceutical industry is highly regulated by the FDA. New drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) & (d).

28. The FDA does not approve a drug for the treatment of a sickness in general (*i.e.*, the FDA does not approve a drug to treat "cancer" generally). Instead, a drug is approved for treatment of a specific condition for which the drug has demonstrated safety and efficacy. The

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specific approved use is called the "indication" for which the drug may be prescribed.

29. Any use other than a drug's specific indication or indications is considered an "off-label" use. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than that described in the drug's labeling. Off-label use includes treatment of a condition not indicated on the label, treatment of the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population.

30. Pursuant to the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-97 (2005) (the "FDCA"), the FDA strictly regulates, *inter alia*, the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs.

31. Brochures, handouts, slideshows and other promotional materials aimed at physicians are deemed to be "labeling" and are regulated accordingly. *See* 21 C.F.R. § 202.1(l)(2).

32. Under FDA regulations, product labeling must be pre-approved by the FDA and conform to exacting requirements concerning, *inter alia*, drug interactions, indicated uses, and claims concerning competing products. *See* 21 C.F.R. § 201.57.

33. All claims made in any labeling must be truthful, not misleading, and represent a fair balance of the information presented.

34. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. *See* 21 U.S.C. §§ 331(a)-(b), 352(a), (f), (n); 21 C.F.R. § 201.57.

35. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the FDCA and regulations

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promulgated pursuant to it. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

- Minimize, understate, or misrepresent the risks, contra-indications, and complications associated with that drug;
- Overstate or misrepresent the risks, contra-indications, and complications associated with any competing drugs;
- Reference "off-label" uses of the drug—*i.e.*, those uses which are not indicated by the FDA—or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;
- Make comparative claims about the drug which have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side-effects, physician preference, or
- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

36. The FDA regulates drugs based on the "intended uses" for such products. A manufacturer who wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for *each* intended use. 21 U.S.C. § 331(d). *See also* 21 U.S.C. §§ 355(a), 360b(a).

37. The pharmaceutical manufacturer must provide information not only on how a product is to be administered, but also on each intended use of the product. 21 C.F.R. § 201.5. The labeling requirements are intended to make drugs safe and effective for all proposed uses.

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See generally 21 C.F.R. §§ 99.1, 201.100 (c), (d). A drug shall be deemed misbranded unless its label bears adequate directions for the approved use. 21 U.S.C. § 352(f)(1).

38. Oral statements and materials presented at industry-supported activities (such as lectures and dinners) provide evidence of a product's intended use. If these statements or materials promote a use that is inconsistent with the product's approved labeling, the drug is misbranded for failure to have labeling with adequate directions for all intended uses. 21 C.F.R. § 99.405.

39. The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. 21 U.S.C. § 355.

40. Although it is not unlawful for physicians to prescribe approved drugs for diseases or at dosages different than those set forth in drugs' labeling, the FDA prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific, governmental body.

41. Legal dissemination of off-label information by a pharmaceutical company is largely limited to responses to *bona fide*, unsolicited inquiries. Pharmaceutical companies may disseminate scientific studies investigating off-label use of a product. When doing so, the manufacturer may disseminate only copies of unabridged, peer reviewed scientific and medical articles. The articles must concern drugs that have been approved for other uses by the FDA, and the information must not be false or misleading. 21 C.F.R. § 99.101. Information is false or misleading when "the information includes only favorable publications when unfavorable

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publications exist . . . or the information presents conclusions that clearly cannot be supported by the results of the study . . . ." 21 C.F.R. § 99.101(a)(4).

42. Any presentations, promotions, or marketing to physicians of products for use other than that approved for labeling purposes by the FDA is considered off-label marketing and generally is prohibited by FDA regulations. *See* 21 U.S.C. §§ 331(a)-(b), 352(a), (f).

43. The Food and Drug Administration Modernization Act of 1997 ("FDAMA") provides a safe-harbor if a manufacturer wishes to market or promote an approved drug for an alternative use (*i.e.*, a use not listed on the approved label). To qualify for the safe-harbor, the manufacturer must, *inter alia*, submit a supplemental application for the new use similar to the application necessary to gain initial approval, 21 U.S.C. § 360aaa-3, disseminate only unabridged articles, 21 U.S.C. § 360aaa-1(a)(1), and prominently display statements that the information concerns a use not approved by the FDA and, if applicable, that there are other treatments that have been approved for that use, 21 U.S.C. § 360aaa(b)(6).

44. Perhaps most importantly, the manufacturer can disseminate information on alternative uses under FDAMA's safe-harbor "*only* if the information . . . is not false or misleading and would not pose a significant risk to the public health." 21 U.S.C. § 360aaa-1(a) (emphasis added).

45. Manufacturers may respond to physicians' truly "unsolicited" requests for information, 21 U.S.C. § 360aaa-6(a), but may not "seed" the audience at promotional events and encourage physicians to discuss or inquire about off-label uses.

46. Strong policy reasons exist for such strict regulation of off-label marketing. Off-label promotion undercuts the FDA's authority by allowing drug manufacturers to bypass the

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agency's strict review and approval process. Off-label promotion also removes the incentive to obtain definitive clinical study data and weakens the goal of evidence-based medicine.

47. Indeed, allowing unchecked off-label promotion will encourage a pharmaceutical manufacturer to seek FDA approval for the product use easiest to establish. If the pharmaceutical manufacturer knows that it can market other uses with impunity, it likely will make its initial application as narrow as possible. The pharmaceutical manufacturer can then conduct only the minimum clinical trials necessary to gain initial approval for one basic use. The many other uses for which the pharmaceutical manufacturer will actively market the drug will not have been proven safe or effective.

48. As detailed below, Defendants' marketing of Trisenox repeatedly violated provisions concerning off-label marketing, which in turn violated the FCA because Defendants' improper off-label marketing corrupted physicians' independent clinical judgment and led them to prescribe Trisenox when they otherwise would not have, and many of those prescriptions were paid for by Medicare and other Government-funded health insurance programs.

(3) The Anti-Kickback Statute

49. A pharmaceutical manufacturer or other entity cannot provide financial incentives to a physician that may undermine the physician's independent medical judgment in prescribing drugs. *See* 42 U.S.C. § 1395nn (a)(1), (h)(6); 42 U.S.C. § 1320a-7a(a)(5); 1320a-7b(b) (the Medicare Fraud & Abuse/Anti-Kickback Statute, which also covers kickbacks affecting the Medicaid program). Nor may a pharmaceutical manufacturer or other entity promote a drug for a use inconsistent with its approved use where such promotion is untruthful regarding the safety and efficacy of the drug. 21 U.S.C. § 331. Nor may a pharmaceutical manufacturer promote off-label use that causes non-reimbursable claims to be presented to Medicare for payment. *See also* 42 U.S.C.§ 1395(a)(1), (g)(1).

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50. The Anti-Kickback Statute:

> is extremely broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

Issuance of Final Rules Implementing the Anti-Kickback Statute, 56 Fed. Reg. 35952 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

51. In 1994, the Inspector General of the Department of Health and Human Services issued a Special Fraud Alert concerning prescription drug marketing practices that violated the Anti-Kickback Statute. Among the improper practices cited by the Inspector General were: drug companies' payment of "research grant[s]" to heavy prescribers of their medications; payments by a drug company to physicians for "studies" of the company's products when the studies were "of questionable scientific value and require[d] little or no actual scientific pursuit;" and payments to physicians where the physicians had offered no particular services or benefit to the drug company but the payment appeared to have been based on the volume of business the doctor generated in the past, or could generate in the future for the drug company. *See* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372 (Dec. 19, 1994).

52. As detailed below, Defendants' marketing of Trisenox repeatedly violated provisions of the Anti-Kickback Statute, which in turn violated the FCA.

(4) Stark Law — The Medicare/Medicaid Self-Referral Statute

53. The Medicare/Medicaid Self-referral Statute is commonly known as the "Stark Law." It prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicare and Medicaid patients to the manufacturer for certain "designated health

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services," including drug prescriptions, 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 claim for such prescriptions. The Stark Law also prohibits payment of Medicare claims for prescriptions rendered in violation of its provisions. 42 U.S.C.§ 1395nn(a)(1), (g)(1).

54. As detailed below, Defendants' marketing of Trisenox repeatedly violated provisions of the Stark Law, which in turn violated the FCA.

(5) Reimbursement by Medicare, Medicaid, Tricare, and FEHBP

55. Medicare is a Federal Government health program for people 65 years of age and older, some disabled people under 65 years of age, and people with End-Stage Renal Disease (permanent kidney failure treated with dialysis or a transplant) that Congress created in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is the nation's largest health insurance program and covers nearly 40 million Americans. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare will not pay for over-the-counter drugs or most self-administered prescription drugs until the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("Medicare Part D") is fully implemented.

56. Under certain conditions, however, Medicare covers drugs such as Trisenox used in association with cancer treatments. Thus, Medicare covers "drugs or biologicals used in an anticancer chemotherapeutic regimen" *when used for their FDA-approved indications*. In certain, specific instances Medicare covers off-label uses of FDA-approved drugs but *only* if the off-label use "is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United

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States Pharmacopoeia-Drug Information . . . ." 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). Regardless of coverage, off-label, as explained above, is prohibited.

57. 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.

58. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

59. The Federal Employee Health Benefit Program ("FEHBP") provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield

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Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

60. As set forth more fully below, Defendants have violated the FCA and other federal statutory and regulatory provisions by not fully disclosing Trisenox's safety profile, by providing illicit inducements, and by promoting Trisenox's off-label uses, thereby causing false claims to be submitted and to be reimbursed by the Government.

B. On-Label Use of Trisenox

61. APL is a specific type of leukemia that affects 10 to 15 percent of the approximately 10,000 patients who are diagnosed with acute myeloid leukemia ("AML") in the United States each year. APL is readily identifiable and distinguishable from other forms of AML (and from other cancers) by the presence of a specific chromosomal abnormality, a translocation (*i.e.*, a switch) of genetic material from chromosome number 17 to number 15. APL is clinically associated with a coagulation disorder that results in excessive blood clot formation that eventually exhausts the blood's ability to clot, leading to internal bleeding. Due in part to this bleeding disorder, APL has been recognized as a distinct clinical entity for over 35 years. As one analysis notes, although APL is a subtype of AML, "because of differences in epidemiology, treatment, prognosis and complications [APL] is considered separately."

62. Trisenox was approved by the FDA on September 25, 2000 for the treatment of APL patients who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, the standard first-line treatment for APL; Trisenox is not FDA-approved for the treatment of any other diseases. Additionally, the FDA has approved *only* a dosage of 0.15 mg/kg per day, for up to sixty days.

63. Trisenox interferes with the growth and spread of APL cancer cells, which are then eventually destroyed by the body's own white blood cells. During all relevant times,

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Trisenox was produced by Defendant CTI.[1] Defendant CTI's marketing was assisted by: Defendant MedComm, which was responsible for providing additional prescribing information about Trisenox to doctors (generally concerning off-label uses); Defendant Envision, which orchestrated meetings with physicians where Trisenox's off-label uses were touted; and the former Documedics (now a part of the Lash Group, an autonomous business unit within Defendant AmerisourceBergen), which helped physicians win reimbursement for their off-label use of Trisenox. Upon information and belief, Defendants MedComm, Envision, and AmerisourceBergen knew that they were facilitating Defendant CTI's unlawful behavior, and are equally culpable for the false claims for Trisenox that were caused to be submitted.

C. Defendants' Illegal Off-Label Marketing and Sales of Trisenox

64. Although Trisenox is FDA-approved only for the treatment of relapsed APL patients, Defendants' promotional materials heavily focused on Trisenox's off-label uses.

65. The domestic market for Trisenox's approved use—*i.e.*, the number of APL patients who have relapsed from their first-line treatment—numbers only in the low hundreds.

66. Because of Trisenox's limited on-label market, Defendants engaged in unlawful off-label marketing of Trisenox to expand its meager sales, pushing Trisenox as a treatment for, *inter alia*, multiple myeloma ("MM"), myelodysplastic syndrome ("MDS"), chronic myeloid leukemia ("CML"), chronic lymphocytic leukemia ("CLL"), and AML (other than APL). Defendants knew that if these off-label markets were tapped, Defendants would receive enormous profits from their off-label sales and promotions of Trisenox.

67. MM, MDS, CML, CLL, and AML are all separate diseases, and treatment appropriate for any one of these diseases is not necessarily appropriate for treatment of the other diseases. The FDA approves drugs for the treatment of each of these diseases separately, and

[1]In 2005, CTI sold Trisenox to Cephalon, Inc.

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only after appropriate clinical trials demonstrating a drug's efficacy and safety for the treatment of each disease.

68. Based on Defendants' marketing materials and conversations with prescribing physicians, Defendants' failure to fully disclose Trisenox's side-effects, their extensive illegal promotion of Trisenox for off-label uses to doctors who would be prescribing Trisenox, and the enormous increase in Trisenox prescriptions and sales during this same time period, it is clear that Defendants improperly and illegally caused non-reimbursable claims to be submitted to (and be paid by) the Government.

(1) Defendants Train Their Sales Force To Push Trisenox's Off-Label Uses

69. Defendants systematically engaged in unlawful off-label marketing.

70. Defendants' off-label marketing scheme is evident from their first Trisenox Sales Meeting held in San Francisco on November 30, 2000—less than two months after Trisenox won FDA-approval as a treatment for relapsed APL patients. At that sales meeting, Trisenox sales representatives were barraged with the message that sales growth should be driven by off-label marketing. For example, in addition to workshops detailing "Reimbursements Strategies in MM," the sales representatives were taught:

- "Expand Trisenox business outside of APL . . . . This will be an ongoing strategy to develop the usage of Trisenox beyond APL and uncover possible research sites."
- "Education! Before we start selling in 'other' areas, lets make sure we know what we are talking about. Know the disease, know the data, know the reimbursement strategies, and most importantly, know your customer!"

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- "MM is a large market for Trisenox." A workshop on the "Multiple Myeloma Clinical Argument" also declared that MM is a "future indication for Trisenox."

Unsurprisingly, after being spoon-fed a strict diet of off-label marketing information from management, Trisenox sales representatives dutifully marketed Trisenox for off-label uses.

71. CTI's Eastern Regional Business Meeting held January 11-13, 2001 in North Miami, Florida heavily emphasized off-label uses of Trisenox. This meeting included, *inter alia*, presentations entitled:

- "MDS Competition and Trisenox Data Review"
- "MM and Trisenox Applications"
- "CML, Maintenance and Trisenox Applications"

72. CTI's National Sales Meeting held in Seattle on June 18-20, 2001 similarly emphasized off-label uses of Trisenox, with no fewer than three presentations on MM (*e.g.*, "Maximizing Trisenox Messages in Multiple Myeloma"), two presentations on MDS (*e.g.*, "Positioning Trisenox in MDS"), and two presentations on CML (*e.g.*, "Expanding the APL Franchise & New Opportunities in CML"). One presentation given at this meeting by CTI's Western Region Business Director Chuck Bucklar and entitled "Trisenox Marketing Strategy" declared that one of CTI's primary marketing goals was to "create a broad awareness in the hematology community *regarding the potential of Trisenox therapy in multiple myeloma and MDS*." (Emphasis added).

73. Defendants' written handouts to sales representatives also emphasized off-label uses. For example, a June 26, 2002 CTI Sales Training memo instructs Trisenox sales representatives to discuss APL and "[t]hen bridge the discussion into . . . MM, MDS, and CML."

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74. Additionally, Defendants distributed selling algorithms to their sales representatives that detailed how to market Trisenox outside of its indicated use.

75. Defendants used these and other off-label marketing tactics to unlawfully increase Trisenox's sales.

(2) Defendants' "Advisory Board" Meetings Are Marketing Events Designed To Highlight Off-Label Uses

76. Defendants invited doctors to attend "Advisory Board" meetings so that Defendants could better promote Trisenox's off-label uses.

77. On April 21, 2001, CTI sponsored the Jacksonville Advisory Board meeting in Ponte Vedra, Florida, an event marketing Trisenox to eighteen area physicians. The meeting emphasized Trisenox as a treatment for MM and MDS, and did not provide a fair balance of information about Trisenox's safety profile.

78. On October 22, 2001, Laura Beggrow, CTI's Central Region Business Director, e-mailed her impressions from the Chicago Advisory Board meeting, managed by Envision. Ms. Beggrow noted that physicians were perplexed that CTI was marketing Trisenox for MDS. She wrote: "A few physicians (during the marketing sessions) were somewhat confused as to why we had a talk on MDS when we have no data to speak of!" Ms. Beggrow also remarked that "because of the time limits [of the meeting] we need to prioritize the messages and points (APL, MM, MDS)." She was "confident that we will accomplish *my main objectives* of this program: penetration of marketplace and *expansion of product usage* . . . ." (Emphases added).

79. On May 4, 2002, Defendants sponsored a "Clinical Advisory Board Meeting" for sixteen physicians at the W Hotel in San Francisco. This marketing meeting was attended by top CTI sales and marketing personnel, and included presentations entitled: "Trisenox in Relapsed APL *and other Leukemias*," (emphasis added), and "Potential Application for [] Trisenox in

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Multiple Myeloma." Presentations on Trisenox's safety profile failed to discuss differentiation syndrome symptoms when Trisenox is used off-label, despite Defendants' full awareness of this side-effect. The presentation binder also contained numerous abstracts (*i.e.*, abridged medical articles) that supposedly support the use of Trisenox off-label—in violation of FDA regulations that dictate that only unabridged articles may be distributed.

80. Because Defendants controlled the content of these "Advisory Board" meetings, off-label marketing that took place at these meetings was illegal.

(3) Defendants' "Advisory Board" Meetings Were Controlled By Defendants, Rendering Off-Label Discussion Impermissible

81. Defendants' "Advisory Board" meetings may have been established in an effort to appear to qualify for an exception to the FDA's off-label marketing restrictions—federal regulations permit discussion of off-label uses of pharmaceuticals at *independent* continuing medical education ("CME") seminars. Such seminars, however, must be truly independent of the drug companies.

82. The Accreditation Council for Continuing Medical Education ("ACCME") has promulgated the Standards for Commercial Support of Continuing Medical Education. Commercial organizations, such as pharmaceutical manufacturers, may provide educational grant money for *educational* events to CME accredited providers.

83. Under the ACCME Standards, the accredited provider is *solely responsible* for "the content, quality and scientific integrity" of the CME activities. The accredited provider—not the pharmaceutical company—must determine program "content, faculty, educational methods and materials." The CME program must be "free of commercial bias for . . . any product." Any discussion of off-label use must make clear that the drug is not FDA-approved for such purposes. Faculty members cannot be paid by the grant-giving pharmaceutical

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company. Any financial interest of the faculty members and the grant-giving pharmaceutical company must be disclosed.

84. Pharmaceutical companies may give "unrestricted grants" to sponsor CMEs, but may not be involved in formulating the content of the presentations, picking the speakers, or selecting the attendees. Defendants violated all of these requirements when conducting their purported CME conferences for the promotion of off-label uses of Trisenox (*e.g.*, Defendants surveyed drug usage data and targeted physicians treating MM and MDS patients as invitees to the seminars, thereby improperly controlling the attendee list, and Defendants created, or at least reviewed and approved, the content of most presentations, thereby improperly controlling the content of the meetings). Even when Defendant CTI retained third-party companies like Defendant Envision to organize the CMEs, CTI continued to control the content, speakers, and invitees to these events.

85. In 2002, CTI hired Envision to handle all regional "Advisory Board" meetings. Thereafter, Envision acted as a conduit for the payments and gratuities paid to the attendees. However, CTI continued to control virtually every aspect of these events. CTI designed and approved the presentations; hand-picked the speakers for the seminars; selected the attendees based on their ability and willingness to prescribe high quantities of Trisenox; and evaluated the presentations to be sure that Defendants' "message" was being delivered. CTI monitored its Return on Investment ("ROI") by following the prescribing patterns of physicians who attended these conferences. Follow-up reports to marketing executives at CTI highlighted that the attendees received presentations regarding Trisenox's off-label uses. These memoranda also reported to senior executives the pledges made by attendees to order more Trisenox for their patients.

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86. For example, the Jacksonville Advisory Board meeting in Ponte Vedra, Florida, on April 21, 2001, an event that marketed Trisenox to eighteen area physicians, belies any notion of impartiality or independence by the presenting physicians. Defendants' notes from that meeting concerning one presenter's (off-label) discussion on MM declare: "He spent too much time discussing 'other therapies'. . . . In the future he will need a little more direction as to where to focus his presentation." In reality, the Advisory Board meetings were off-label marketing meetings organized, controlled, and paid for by Defendants.

87. Defendants' disregard of applicable regulations on off-label promotion renders Government reimbursement of Trisenox prescriptions that were influenced by these "Advisory Board" meetings false and in violation of the FCA.

(4) Defendants Marketed To Physicians Who Would Rarely, If Ever, Treat APL Patients

88. APL simply does not affect enough people to justify economically the size of Defendants' marketing efforts (CTI employed more than 40 sales representatives in 2002) - unless those efforts were focused on diseases other than APL.

89. Defendants focused their marketing efforts on physicians whose practices would rarely - if ever - prescribe Trisenox for FDA-approved uses. Given APL's rarity, on information and belief, most APL patients are treated in large academic research-based cancer treatment centers.

90. Instead of seeking APL patients at large academic research-based cancer treatment centers, Defendants' sales representatives targeted physicians affiliated with community hospitals - many of whom have never seen or treated an APL patient. Not coincidentally, according to Defendants' own data, more than ¾ of MDS and AML patients are

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treated at community hospitals, precisely where Defendants' sales representatives were marketing Trisenox off-label for, *inter alia*, MDS and AML.

91. Unsurprisingly, most of Trisenox's revenues are derived from off-label sales for MM and MDS.

92. Defendants' marketing to physicians, many of whom are affiliated with community hospitals and rarely if ever treat APL patients, is clear evidence of Defendants' illegal off-label marketing scheme.

(5) Defendants Recommend Dosing At Nearly Double FDA-Approved Levels

93. Trisenox is indicated for a dosage of .15 mg/kg/day. Any other dosing schedule is considered off-label.

94. A June 26, 2002 CTI Sales Training memo informs Trisenox sales representatives that CTI has a better understanding of the chemistry of Trisenox, "which has changed our dosing rationale moving forward." The memo directs the sales representatives to encourage physicians to follow a .20-.25 mg/kg/day dosing schedule, at least at the beginning of treatment, despite the fact that "we have no data at the present time to support this dose and schedule."

95. CTI sales representatives, at Defendants' direction, pushed this increased off-label dosage, even when they had difficulty explaining the rationale for the increase. Richard Cady, CTI's National Sales Trainer, suggested to one OAM that despite the absence of a "specific article that provides th[e] rationale" for increasing dosage from the on-label .15 mg/kg/day to the off-label .25 mg/kg/day, she should "use the new [M]edcom[m] document that lists all of the clinical trials with their schemas on an excel spreadsheet." This marketing was not FDA-approved, clearly off-label, and apparently based in-part on the dosages that certain physicians were using in clinical trials. Obviously, this new dosage had not been proven safe or

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effective in a controlled clinical study, and Trisenox remains indicated only for a dosage of .15 mg/kg/day.

96. Defendants marketed elevated dosages of Trisenox in order to increase sales.

97. Defendants' (off-label and hence illegal) recommendation to dose at .25 mg/kg/day increased Trisenox sales by more than 65% compared to the indicated dose of .15 mg/kg/day. Because Trisenox was packaged so that each vial would contain enough of the drug for one dose at the approved level, the off-label use of .25 mg/kg/day resulted in the sale and use of two or three vials instead of just one vial.

(6) Defendants Failed To Inform Doctors Of Side-Effects Caused By Trisenox, Including Differentiation Syndrome Symptoms In Non-APL Patients

98. The information Defendants provide in their promotional materials is false, misleading, or incomplete regarding Trisenox's safety profile. At their sponsored lunches and dinners with prescribing physicians Defendants incompletely described the potential adverse effects of Trisenox—especially differentiation-like syndrome associated with Trisenox's off-label use.

99. Differentiation syndrome, also called ATRA syndrome or retinoic acid syndrome, is characterized by dyspnea with or without exertion (*i.e.*, breathing discomfort or significant breathlessness), sudden weight gain, and sudden fever, and is often fatal if not treated. Most patients who experience differentiation syndrome are effectively treated with prompt administration of steroids. Patient education for APL patients involves emphasizing the importance of daily weight measures and monitoring shortness of breath and other changes. Patients must seek immediate treatment of differentiation syndrome if any of these symptoms occur.

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100. Defendants know that differentiation syndrome occurs in APL patients, yet Defendants did not inform physicians to whom Defendants were marketing Trisenox's off-label uses—physicians who had no reason to expect differentiation syndrome could occur in non-APL patients—that Defendants knew of incidents of *symptoms* similar to differentiation syndrome when Trisenox had been used off-label as a treatment for, *inter alia*, MM, MDS, CML, CLL, and AML.[2]

101. Defendants knew, at least as early as March 4, 2002, and on information and belief even earlier, of differentiation syndrome symptoms occurring in non-APL patients when Trisenox was used off-label to treat those patients, yet failed to disclose these side-effects. For example:

- on March 4, 2002, Peter Sportelli, CTI's Director of Sales, acknowledged in an internal, non-public e-mail that "some non-APL patients have experienced a differentiation-like side[-]effect";
- on March 11, 2002, Sharon Summerfield, CTI's Medical Service Liaison, admitted in an internal, non-public e-mail that "[a] syndrome similar to the 'APL differentiation syndrome' has been noted in p[atients] other than APL p[atients] who are on [Trisenox]";
- a June 26, 2002 CTI Sales Training internal, non-public memo notes that there is "a suggestion of a syndrome that looks like APL differentiation syndrome when Trisenox has been used [off-label]," but does not direct the sales force to warn physicians about this condition;

[2]It is unclear whether differentiation syndrome actually can occur in patients who do not have APL, given the mechanisms of both diseases. Regardless, CTI failed to disclose that patients treated with Trisenox had developed *symptoms* similar to the symptoms of differentiation syndrome (*i.e.*, symptoms like fever, breathing difficulty, heart and lung problems, fluid retention, and weight gain).

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- on July 15, 2002, Jack Singer, CTI's Medical Director and one of CTI's founders, conceded in an internal, non-public e-mail that "we have seen differentiation syndrome in other diseases including MDS, myeloma, and prostate"; and
- on or about September 25, 2002, Defendants privately admitted to Relator that differentiation syndrome symptoms occur in 20 to 25 percent of non-APL patients treated with Trisenox.

Defendants knew of numerous incidences of differentiation syndrome symptoms in non-APL patients, yet failed to inform physicians of these side-effects.

102. Despite Defendants' awareness of differentiation syndrome symptoms in non-APL patients at least as early as March 4, 2002, Defendants failed to inform prescribing physicians of these side-effects.

103. On July 15, 2002 Jamie Czajkowski, CTI's Northeast Regional Business Director, accompanied Relator on his marketing calls. Relator refused to discuss any off-label uses of Trisenox. Mr. Czajkowski made representations to Paula Campagnia R.N and Dr. Topilow of Atlantic Hematology Oncology Group in New Jersey that Trisenox was safe and effective in MDS and that they should prescribe it at 0.25mg/kg/day because that was the appropriate dose. Both the suggested usage in MDS and the dosage amount were off-label marketing. Relator ordered a fact-sheet from MedComm on safety and specifically on APL syndrome for the Atlantic Hematology Oncology Group, but did not participate in the conversation because of its illegal nature. Dr. Campagnia treated the MDS patient with Trisenox based upon Mr. Czajkowski's statements. The MDS patient died of symptoms similar to differentiation syndrome. Relator later learned that the additional information he ordered from MedComm

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failed to address Trisenox's side-effects in non-APL patients. CTI fired Relator shortly after his submission of this account on an Adverse Experience form.

104. On information and belief, scores of other patients treated with Trisenox for off-label uses unnecessarily have suffered side-effects because of CTI's failure to warn physicians about those side-effects.

105. Defendants also knew that Trisenox may cause thrombocytopenia, a disorder in which blood does not contain enough platelets, leading to difficulty in clotting and sometimes associated with abnormal bleeding, yet failed to disclose that harmful side-effect. As Jack Singer noted in an internal, non-public email on May 8, 2002, "[i]n reviewing the data, there may be some thrombocytopenia from Trisenox in patients with low marrow reserve."

106. Defendants' failure to adequately describe Trisenox's side-effects evidences Defendants' failure to present a fair balance of information and demonstrates the lengths to which Defendants went to illicitly promote Trisenox. Defendants' misrepresentation of the drug's safety, combined with their aggressive off-label marketing, and use of improper inducements, caused Trisenox prescriptions to be written in situations where—had the prescribing doctors been fully aware of the circumstances—those prescriptions would not have been written. Such prescriptions that were reimbursed by Medicare and other Government-funded health insurance programs constitute false claims under the FCA.

107. On information and belief, Defendants' wrongful conduct concerning Trisenox has been ongoing from the time of its FDA approval in September 2000 through until Cephalon, Inc.'s purchase of Trisenox in 2005.

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(7) Defendants Misrepresented Study Results and Misled Physicians Concerning Trisenox's Safety and Efficacy

108. On information and belief, Defendants skewed data from investigative studies of new uses of Trisenox to make Trisenox appear to be a more suitable treatment for various off-label indications than was actually the case.

109. On information and belief, Defendants regularly failed to disclose side-effects and adverse events seen in investigative studies, making Trisenox appear safer and more tolerable than was actually the case.

110. On information and belief, Defendants excluded non-responsive patients for "protocol violations" so that the studies' results would have greater (or any) statistical significance, thereby increasing Trisenox's perceived efficacy.

111. Defendants' publications describing the investigative studies at conferences like the annual American Society of Hematology ("ASH") conference were mere abstracts that failed to report side-effects, drop-out rates, or other factors that negatively impact efficacy.

112. Defendants rewarded physicians charged with conducting the investigative studies with lucrative speaking fees, thereby attempting to influence these physicians' clinical judgments by rewarding "favorable" results.

113. Defendants created misleading abstracts and reports from the studies to promote Trisenox off-label.

114. These misleading abstracts and reports gave the false impression that Trisenox was both more effective and had fewer harmful side-effects than was actually the case when used off-label.

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(8) Defendants' Off-Label Marketing Of Trisenox Is Not Permitted Under FDAMA's Safe-Harbor

115. Defendants' off-label promotion of Trisenox is not permitted under FDAMA's safe-harbor provisions.

116. FDAMA's safe-harbor allows marketing for alternative uses, provided that the manufacturer meets certain stringent requirements. *See supra* ¶¶ 43-45. *See also* 21 U.S.C. § 360aaa-1.

117. Defendants did not submit a supplemental application for any of the new uses emphasized in their marketing, and thereby did not comply with the FDAMA safe-harbor provision codified at 21 U.S.C. § 360aaa-3.

118. Defendants disseminated abridged abstracts supporting Trisenox's off-label uses, and thereby did not comply with the FDAMA safe-harbor provision codified at 21 U.S.C. § 360aaa-1(a)(1). Defendants also failed to submit any of these abstracts or other off-label materials presented at their "Advisory Board" meetings to the FDA for approval.

119. Defendants did not prominently display statements that the information concerning off-label uses concerns uses not approved by the FDA, and, where applicable, did not prominently display statements that there are other treatments that have been approved for those uses, and thereby did not comply with the FDAMA safe-harbor provision codified at 21 U.S.C. § 360aaa(b)(6).

120. Most crucially, Defendants disseminated information on alternative uses that was false and misleading and posed a significant risk to the public health because Defendants did not disclose the incidence of differentiation syndrome symptoms in non-APL patients and other harmful side-effects, and thereby did not comply with the FDAMA safe-harbor provision codified at 21 U.S.C. § 360aaa-1(a)(2).

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121. Relator initially cooperated with Defendants' marketing efforts based on Relator's mistaken belief that Defendants were pursuing large-scale clinical trials (known as the IMPATH protocol) and were going to pursue Supplemental NDAs for disease states like MM, MDS, CML, and APL.

122. When Relator learned that CTI halted the IMPATH protocol, he suspected that Defendants were not going to comply with the FDAMA safe-harbor requirements, feared that Defendants' off-label marketing was unlawful, and immediately began raising this issue with Defendants.[3]

123. On December 13, 2001, Relator e-mailed Carolyn Paradise, CTI's Executive Vice President of Clinical Development, and cc'ed Mark Levonyak, CTI's Director of Marketing, and Katie Schroeder, CTI's Vice President of Sales, Marketing, and Operations, to express his concerns that CTI might be violating FDA marketing regulations, specifically a regulation that "restrict[s] promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and [] preclude[s] commercialization of the drug before it is [FDA-]approved for commercial distribution." *See* 21 C.F.R. § 312.7(a) (2005).

124. Relator was chastised for raising these issues both by Peter Sportelli, who commented that "you certainly aren't making any friends on this email," and by Carolyn Paradise, who noted that "[t]here are too many Chinese whispers in this company" and who discouraged Relator from creating any type of paper-trail. Ms. Paradise wrote in response to Relator's December 13, 2001 e-mail: "e-mails of this nature are discoverable and we should discuss such opinions over the phone."

[3]Relator first began to suspect that Defendants were being untruthful in or around December 2001, and investigated his suspicions over the next several months before confirming them in or around mid-2002.

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125. As Relator learned more facts that supported his suspicion that Defendants were engaging in unlawful practices, he ceased participating in such activities and continued raising warning flags. Relator was demoted and eventually terminated on or about September 27, 2002 for his investigation of and attempts to end the false claims that were caused to be submitted by Defendants. Defendants' retaliation against Relator, who sought to expose and correct Defendants' unlawful behavior, violates the FCA's anti-retaliation provision. *See* 31 U.S.C. § 3730(h).

D. Illegal Medicare Reimbursement for Trisenox

126. In early 2001, CTI learned that the APL market was much smaller than expected. Instead of the approximately 600 patients that CTI projected, fewer than 300 patients were potential consumers of Trisenox for its on-label use. Therefore, CTI's sales of Trisenox were substantially lower than projected.

127. CTI asked its OAMs to brainstorm methods to increase sales, and the OAMs were required to present these ideas to CTI management.

128. Relator was asked by CTI management to research Investigational New Drug ("IND") applications and reimbursement possibilities pursuant to IND protocols.

129. While performing this research, Relator learned that certain cancer therapies like Trisenox could be reimbursed by Medicare if the drug had been approved for any indication by the FDA and the off-label use for which reimbursement was sought "is supported by one or more citations which are included (or approved for inclusion) in . . . the United States Pharmacopoeia-Drug Information . . . ." 42 U.S.C. § 1395x(t)(2)(B)(ii)(I).

130. The relevant section of 42 U.S.C. § 1395x reads as follows:

§ 1395x. Definitions

For purpose of this title [42 USCS §§ 1395 et seq.]--

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(t) Drugs and biologicals.

(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2) of this section, include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2) (A) For purposes of paragraph (1), *the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B))*.

(B) In subparagraph (A), the term *"medically accepted indication"*, with respect to the use of a drug*, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—*

(i) the drug *has been approved* by the Food and Drug Administration; *and*

(ii) (I) *such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia*: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, *the United States Pharmacopoeia-Drug Information*, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs.

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42 U.S.C. § 1395x (emphases added).

131. The United States Pharmacopoeia-Drug Information ("USPDI") contains three volumes. Relevant to the instant case, Volume I of the USPDI describes certain uses of drugs, including off-label uses that are accepted by research and other data. Volume III of the USPDI lists drugs along with special designations they possess, including orphan drug status, without regard to the safety or efficacy of those drugs.

132. Relator learned that Trisenox was listed in Volume III of the USPDI based on Trisenox's orphan drug status for certain diseases, including MM and MDS. Relator believed that Trisenox's listing in Volume III of the USPDI qualified it for Medicare reimbursement under 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). *It does not*. Listing in Volume III of the USPDI *is not* equivalent to listing in Volume I of the USPDI, and drugs or usages listed only in Volume III are *not* reimbursed by Medicare.

133. Physicians and medical professionals familiar with Medicare reimbursement are well aware that a listing in Volume I of the USPDI confers Medicare reimbursement while a listing in Volume III does not provide Medicare reimbursement.

134. Any experienced physician or medical professional not aware of the difference between listing in Volume I and listing in Volume III of the USPDI is reckless in his ignorance of Medicare reimbursement policy.

135. Relator, an inexperienced sales representative who had not been employed at CTI for even one year, suggested (albeit mistakenly) to senior management at CTI that because Trisenox was listed in Volume III of the USPDI, Medicare may reimburse for Trisenox's off-label use to treat, *inter alia*, MM and MDS.

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136. Senior management at CTI—including, *inter alia*, Rick Cady, Mark Levonyak, Katie Schroeder, Peter Sportelli, Carolyn Paradise, and Jack Singer, the last two of whom are highly experienced hematologists—knew, or was reckless in not knowing, that a listing in Volume III of USPDI *does not* confer Medicare reimbursement.

137. Nevertheless, the aforementioned senior management of CTI, with the assistance of CTI's hired reimbursement specialist Documedics, illegally pursued Medicare reimbursement for off-label uses of Trisenox listed in Volume III—but not Volume I—of the USPDI.

138. Senior management at CTI was motivated to pursue illegal Medicare reimbursements for off-label uses of Trisenox because they knew that Trisenox's on-label sales were anemic and knew that off-label sales would only increase if doctors and patients could obtain reimbursements for those uses.

139. CTI regularly took a cavalier attitude towards (non)compliance with applicable laws and regulations. As one senior manager analogized: "If you are going to be stopped for speeding, it is better to be doing 80 m.p.h. in a 55 m.p.h. zone, not 56 in a 55."

140. All Medicare reimbursements of Trisenox for off-label uses were thereby fraudulently obtained, improper, illegal, and constitute false claims that were caused by Defendants and were paid by the Government.

E. Defendants' Illegal Inducements To Prescribing Physicians Violate The Anti-Kickback Statute

141. Defendants routinely pay physicians inducements masquerading as "honoraria" to attend meetings and dinners promoting Trisenox. In violation of the Anti-Kickback Statute, Defendants have made hundreds of these payments to physicians for the purpose of having physicians either recommend the prescription of Trisenox or order Trisenox. Defendants were well aware that these activities were unlawful.

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(1) Defendants Provided Improper Compensation To "Consulting" Physicians

142. Under the guise of sham "consulting agreements" Defendants paid physicians to attend dinners or conferences and listen to presentations regarding off-label uses of Trisenox. Under the fiction that these physicians were acting as consultants, Defendants routinely paid these physicians significant amounts of money—usually in the range of $500 each for attending a three-hour event. Defendants' employees and/or physicians hired by Defendants for the purpose of promoting Trisenox off-label presented at these meetings.

143. The "consultant meetings" were not held for the purpose of providing Defendants with expert or independent advice. In many cases Defendants did not even record the alleged "advice" provided by the alleged "consultants," and what was considered to be "advice" was never acted upon or reviewed. The "consultants" had no real obligations to Defendants—other than to attend and absorb the off-label marketing pitches.

144. Defendants routinely monitored the number of new off-label patients who were prescribed Trisenox by their "consulting" physicians. Defendants monitored their ROI from these dinners and meetings, and CTI's National Sales Directors prepared monthly reports itemizing their ROI from the dinners and meetings. As Laura Beggrow noted on October 21, 2001 following an "Advisory Board" meeting in Chicago: "I will continue to track and monitor all ROI following this program and provide this information on my monthly report."

145. A typical consultant meeting or dinner was held at a luxury Boston restaurant, arranged by CTI employee Chuck Stevens. Defendants invited numerous physicians and paid each attendee $400 "for attending *and for committing to discuss Trisenox*." (Emphasis added). CTI spent a total of $1,600 on this event. Defendants noted that "You Bet!" there was a ROI from that meeting.

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146. Another typical dinner was held at the Ritz Carlton in Philadelphia on Thursday, August 23, 2001. CTI invited numerous physicians to share and discuss current data in Trisenox, and paid each attendee $500. Senior executives at CTI were present at the dinner and CTI monitored its ROI from this dinner.

147. Defendants also provided monetary incentives to doctors who were high-prescribers of Trisenox by paying them lucrative fees for speaking at meetings promoting Trisenox. Defendants routinely paid $1,500 per lecture for doing little more than discussing Trisenox - and especially its off-label uses.

148. The speaking fees were remuneration for past high-prescribing and inducements to write future prescriptions for off-label uses of Trisenox. The benefits were also inducements to influence the high-prescribing speakers to vigorously tout the off-label uses of Trisenox to audiences of influential physicians.

149. Defendants were shameless in tying their off-label promotion to the purported "honoraria." In or about late 2001, Peter Sportelli instructed CTI sales representative Vince Prieto at a conference in Philadelphia that he needed to insure that physicians were going to use Trisenox off-label before giving them their "honoraria." Obviously, a quid pro quo like this directly violates the Anti-Kickback Statute.

150. Defendants promoted Trisenox's off-label uses by providing financial incentives to physicians for prescribing and speaking on behalf of those non-approved uses. Defendants also minimized Trisenox's side-effects, despite full knowledge of those side-effects. Consequently, Defendants caused prescriptions for Trisenox to be written when they otherwise would not have been written, and caused Medicare and other Government-funded health insurance programs to pay fraudulent, non-reimbursable claims.

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(2) Defendants' Provided "Grants" That Were Thinly-Veiled Rewards For Prescribing Trisenox

151. Defendants made outright payments to physicians and medical facilities in the form of grants to reward those physicians who demonstrated that they were advocates and active prescribers of Trisenox. CTI sales managers identified key doctors who actively prescribed Trisenox and programs that were willing to host Trisenox speakers, and encouraged such persons or programs to obtain "educational grants" from CTI.

152. The large grants ostensibly were given to fund clinical studies, but these studies did not involve significant work for the physicians. Oftentimes they required little more than collating and writing up office notes or records.

153. These grants were charged to the Trisenox marketing budget, and constitute rewards or kickbacks for the recipients' advocacy and prescribing of Trisenox.

(3) Kickbacks Are Illegal And Diminish Patient Care

154. Federal statutory and regulatory law prohibits kickbacks for the promotion of drug usage. A pharmaceutical manufacturer may not offer remuneration in any form to a beneficiary that the company knows or should know is likely to influence the beneficiary to prescribe items from a particular supplier. 42 U.S.C. §§ 1320a-7a(a)(5), 1320a-7b(b).

155. Kickbacks have the effect of reducing a patient's healthcare choices as unaware (and occasionally unscrupulous) physicians steer the patient to off-label products based on the physician's own financial interests, rather than the patient's medical needs. More basically, kickbacks undermine the physician's independent medical judgment as to the appropriate course of treatment.

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156. Defendants' improper compensation of their "consulting physicians" and compensation of doctors who attended lunch or dinner meetings promoting Trisenox constitute violations of the Anti-Kickback Statute and the FCA.

(4) Stark Law Violations

157. Defendants provided significant incentives in the form of lucrative and frequent fees to doctors who were high-prescribers (or potential high-prescribers) of Trisenox. The fees rewarded the doctors for prescribing Trisenox for off-label uses and for advocating such uses to other physicians. Under the Stark Law, Defendants should not have been providing remuneration and incentives for those referrals.

158. Defendants' illegal largesse undermined the independence and accuracy of the information provided to their hand-picked audience of Trisenox prescribers and promoters.

159. Defendants' improper compensation of their "consulting physicians" and compensation of doctors who attend lunch or dinner meetings promoting Trisenox constitute violations of the Stark Law and the FCA.

F. False Claims Caused By Defendants' Scheme Are Readily Identifiable

160. Defendants closely monitored uses of Trisenox and have complete records concerning Trisenox's off-label use and prescriptions for off-label uses that were reimbursed by the Government.

161. Relator has direct knowledge that Defendants know of certain prescriptions for off-label uses of Trisenox that were caused to be written by Defendants' unlawful marketing scheme and that were reimbursed by the Government. Defendants have detailed records concerning which physicians prescribed Trisenox (and often for which off-label use it was prescribed), and the date and the location of these prescriptions. These prescriptions were

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written for Trisenox for off-label uses because of Defendants' unlawful off-label marketing, and these prescriptions were wrongfully reimbursed by the Government.

G. The LASH Group's Role in CTI's Off-Label Marketing Scheme

162. Shortly after Trisenox was launched during the Fall of 2000, CTI embarked on a massive, off-label marketing campaign for its newly market-approved drug. During this period, CTI management was drawn to Relator Marchese's idea that, because manufacturers are eligible to receive grant money to conduct clinical trials for their FDA-approved, orphan designated drugs, Trisenox's off-label uses might be also eligible for reimbursement from Medicare and other Government-funded health insurance programs. CTI's former reimbursement services provider, Epinomics, Inc. ("Epimonics"), questioned whether or not efforts to obtain such reimbursement would lead to the submission of fraudulent claims to Medicare and other Government-funded health insurance programs for Trisenox coverage.

163. With these conflicting opinions, CTI sought clarification on the matter and replaced Epinomics with the former Documedics, now The Lash Group ("LASH"), because they were well known among pharmaceutical manufacturers for their expertise in providing reimbursement services with respect to oncology drugs. Unlike Epinomics, LASH readily embraced Marchese's idea that Trisenox's orphan drug designation could lead to off-label reimbursement. What is more, LASH single-handedly derived from this idea a fraudulent marketing scheme whereby it would deceptively characterize the fact of Trisenox's orphan drug status as a lawful basis upon which to obtain reimbursement from Government-funded health insurance programs for off-label uses of the drug.

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(1) LASH's Fraudulent Manipulation of Trisenox's Orphan Drug Listing to Obtain Illegal Reimbursements From Medicare

164. When LASH began providing services to CTI in or about January 2001, LASH knew that Trisenox had FDA marketing approval solely for its indicated use in treating APL. CTI also had orphan drug exclusivity for this approved use. By definition, orphan designated drugs are used to treat rare disorders that afflict limited populations (*i.e.*, limited markets). 21 U.S.C. § 360bb(b)(2). In early 2001, there were only about 200-300 patients nationwide being treated for APL. *See supra* ¶ 2. Even though Trisenox was only market-approved for use in APL, LASH pitched to CTI the idea that Trisenox's other orphan designations in MDS and multiple myeloma ("MM") could be clinically accepted, and therefore reimbursable in the future. LASH, was also well-versed in the medical literature concerning cancer treatment and understood that the most promising off-label indication for Trisenox was in chemo-resistant MM.

165. LASH was likewise aware that many anti-cancer therapies were being widely prescribed by physicians for off-label uses and, more importantly, were being covered by insurance carriers, including Medicare, when listed in Compendia and in other limited circumstances. Based on its experiences with other drug manufacturers, LASH knew that reimbursement could be a powerful means through which to attract providers and patients to CTI's new drug. Therefore, in order to expand the market for Trisenox, LASH and CTI attempted to craft a reimbursement program that focused on Trisenox's potential off-label uses in treating many other types of cancers, such as MM, MDS, CML, CLL, and AML. *See supra* ¶ 66.

166. By statute, Medicare must provide coverage for those drugs used in an anticancer chemotherapeutic regimen for a "medically accepted indication." 42 U.S.C. § 1396x(t)(2). Usually, a "medically accepted indication" does not include off-label uses. However, an

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exception is made for anti-cancer drugs, such as Trisenox, whereby coverage for an unlabeled use "**must not be denied based solely on the absence of FDA approved labeling for the use.**" (emphasis added). Medicare Carriers Manual, Part 3, §2049.4.C (2002); Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," § 50.4.2 (2007). In the case of off-label uses of anti-cancer drugs, "medical acceptance" can be determined where such a use is supported by a drug's monograph that lists the off-label use as "accepted" in any of the FDA-recognized Compendia (*e.g.*, AHFSDI and USPDI), or supported by Clinical Research appearing in peer-reviewed medical literature **and** is **not listed** as **"not indicated"** in any of the FDA-recognized Compendia. (emphasis added) *See* 42 U.S.C. § 1396x(t)(2)(B); Medicare Manual, §2049.4.C (2002); § 50.4.5 (2007).

167. While LASH understood CTI's desire to gain FDA approval for as many off-label indications as possible, it also understood that CTI wanted to achieve this as quickly as possible so that it could capitalize on Trisenox's seven-year market exclusivity period afforded by its orphan drug status. *See* 21 U.S.C. § 360cc(a). The problem was that both CTI and LASH knew that neither of the requirements stated above, had been met. In order to pursue approval to lawfully market Trisenox for other indications, CTI would have had to file an NDA or IND for **each** indication, which is time-consuming and costly. By way of example, Trisenox was orphan drug designated for use in APL in March 1998, yet it was not granted market approval and thus its market exclusivity in APL until September 25, 2000. Further, after having received marketing approval for Trisenox in September 2000, CTI was still conducting clinical trials to support off-label uses with early results proving the most promising in chemo-resistant MM.

168. However, there was no published peer-reviewed study to support use in MM, or in any other potential off-label use of Trisenox. Moreover, because the stringent guidelines

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imposed by each of the Compendia's reviewing boards also require published studies showing a drug's effectiveness in off-label uses before listing the drug as "medically accepted," CTI did not anticipate getting a listing in any of the FDA-recognized Compendia until well into 2002. Thus, CTI needed to find another way to tap into the off-label markets for Trisenox in order to maximize its full market potential.

169. During the summer of 2001, it became readily apparent to LASH and Relator Marchese that Trisenox's additional orphan designations in MM and MDS were also the very off-label uses for which CTI was seeking reimbursement. Relator Marchese, who had been tasked with finding a way to get off-label use coverage, suggested to CTI management that it might be possible to get reimbursement from Medicare and the other Government-funded health insurers to cover its orphan-designated, off-label uses since a manufacturer could get grant money for conducting clinical trials using orphan-designated drugs. CTI, receiving confirmation from LASH that this was a plausible approach, seized upon this idea immediately.

170. However, rather than put Relator Marchese in charge of this project going forward, CTI management put Shawn Gilbertson, the direct report to Vice President of Sales, Marketing and Operations, Katie Schroeder, in charge of the LASH account (then Documedics) to carry out the necessary steps in seeing this through. Additionally, CTI management prevented Relator Marchese from having any further direct contact with LASH regarding this plan. Marchese later would learn that CTI and LASH intended to obtain reimbursement for off-label uses of Trisenox not through the clinical trial process, but by misrepresenting to providers that such off-label uses were medically accepted.

171. CTI's off-label scheme was premised on its mischaracterization of the FDA-recognized Compendia, USPDI, which has three volumes, of which Volumes I and III are

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relevant. Volume I, entitled "Drug Information for the Health Care Professional," alphabetically lists the drug information monographs and other information, including its accepted indications. So long as a drug's monograph states which indications are "accepted" -- market-approved and off-label -- Medicare must provide coverage for the drug. 42 U.S.C. § 1396x(t)(2)(B); Medicare Manual, § 2049.4.C (2002); § 50.4.2 (2007). Volume III, entitled "Approved Drug Products and Legal Requirements," however, contains the entire text of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" - more commonly known as the "Orange Book." The Orange Book is simply a list of **all** drugs with an effective application (NDA or ANDA) - *i.e.*, FDA approved - as required by law. *See* 21 U.S.C. § 355(j)(7). The Addendum to the Orange Book, also contained in Volume III, includes exclusivity data (*e.g.*, orphan drug status) and patent information for those listed drugs.

172. Seeing an opportunity to exploit language in the statute and Medicare policy which reads, simply, "citation[]… in…[USPDI]" LASH convinced CTI management that Trisenox could appear to be listed as medically accepted in the FDA-recognized Compendia via USPDI even without fulfilling the published study requirement for the listing, which LASH and CTI knew had to be met. However, LASH was well aware that the only reason Trisenox was listed in the USPDI was because of its Orange Book listing as published in Volume III. That Trisenox has orphan drug exclusivity does nothing more than tell competitors that the FDA will not approve a new application covering the same drug until after the 7-year exclusivity period expires (in this case September 2007). 21 U.S.C. § 360cc(a). As an expert in reimbursement services, LASH held itself out as being up to date on the rules and policies governing Medicare reimbursement as stated above. Thus, when LASH helped CTI down this path it knew or acted in reckless disregard of the fact that this method in gaining reimbursement was unlawful.

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Furthermore, given Relator's junior status at CTI and the relative expertise of LASH with respect to these issues, Relator had every reason to rely on LASH's representations, as he did.

(2) LASH's Fraudulent Exploitation of the ACCC Trade Publication to Carry Out Defendants' Off-Label Marketing Scheme

173. Now that LASH had created an apparent solution for the Compendia listing problem, CTI still needed to alert doctors to the fact that Trisenox was reimbursable by the Government-funded health programs (including Medicare), and also have documentation to provide to the directors of these Government programs to support this position. While Relator Marchese had initially suggested sending the letters from the FDA granting Orphan Drug Designation for the particular off-label use as the supporting documentation LASH advised CTI that notice to doctors ***and*** documentation could be accomplished by getting Trisenox listed in the trade publication put out by the Association of Community Cancer Centers entitled, "ACCC Compendia-Based Drug Bulletin."

174. This ACCC publication is more widely read by doctors than the FDA-recognized Compendia. The publication, consisting of approximately 20-25 pages, is distributed to every oncologist and hematologist in the United States for free, while the USPDI is a costly, three-volume text, several hundreds of pages long. LASH knew that the ACCC publication would be an efficient marketing tool for Trisenox's off-label uses, and knew that providers do not expend the time and effort to rely on the Compendia texts themselves. As such, LASH in this way encouraged CTI to pursue getting Trisenox listed in the ACCC publication as a means of getting doctors to recognize that this drug could be prescribed for off-label uses, despite the fact that it was only approved for use in APL patients. At LASH's choosing, the ACCC Drug Bulletin was to be sent to the state Medicare Medical Directors as the supporting documentation, rather than to use the FDA letters as suggested by Relator Marchese.

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175. In October 2001, Relator Marchese was asked by Shawn Gilbertson to draft a letter to the states' Medicare Medical Directors notifying them of Trisenox's new "compendia listing." The letter was to be sent along with the November 2001 ACCC publication. Following LASH's advice that a listing in USPDI-Volume III was sufficient for "compendia-listing," and thus for reimbursement, Relator Marchese wrote:

> Dear Medicare Medical Director,
>
> Attached is a copy of the Compendia based Bulletin published by the ACCC. It details the diseases and therapies listed in the recognized Compendia (USP and AHFS). I would like to bring your attention to the fact that **TRISENOX** is newly listed in the Compendia for the following diseases: *acute myeloid leukemia subtype M-3, multiple myeloma, myelodysplastic syndrome and chronic myeloid leukemia*. **It has achieved listing through FDA approved Orphan Drug Designation.** As you are undoubtedly aware, Medicare traditionally covers Compendia listed products. Therefore, CTI is formally requesting a formulary listing in you [*sic*] state/states. Given the FDA expressed desires [*sic*] to increase patient access to Orphan Designated drugs and its compendia listing, immediate formulary approval is appropriate. The aforementioned diseases are burdensome enough without treatment delays or interruptions due to coverage issues or delays in database upkeep. While this product has very limited usage it represents an important therapeutic options [*sic*] for many patients, hence CTI want [*sic*] to ensure that all the carriers are updated and aware of its new and enhanced reimbursement status. (emphasis added).

176. Though it knew otherwise, LASH never corrected Relator Marchese's good-faith belief that achieving a compendia listing via Orphan Drug Designation conferred an "enhanced reimbursement status." Rather, LASH's primary account representative, Adam Gillette, and Mr. Gilbertson, seized upon certain language in Relator Marchese's draft, and re-wrote the letter in such a way as to ensure that Medicare carriers would not question Trisenox's illusory compendia listing.

177. Notably, Defendants CTI and LASH placed the Relator's name on the modified letter, but never gave him an opportunity to review it, nor asked that he sign it before it was

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distributed to Medicare directors. Defendants were well aware that Relator would never have signed off on the modifications because, as illustrated below, the modifications were calculated to distort Relator's original language, which stated simply that the USPDI listing was achieved "through FDA approved Orphan Drug Designation."

178. The version of the letter ultimately sent in LASH's name along with a copy of the November 2001 ACCC publication stated:

> As a consultant to cancer practices, I would like to take this opportunity to notify you of an update within the **Compendia-Based Drug Bulletin** for November 2001, Fall Update Vol. 10 No. 3, published by the ACCC. It details the diseases and therapies listed in the recognized **Compendia (USP DI)**. I would like to bring your attention to the fact that **TRISENOX™** (arsenic trioxide) is newly listed in the Compendia for the following diseases: *multiple myeloma, myelodysplastic syndrome, chronic myeloid leukemia, in addition to the approved indication of acute myelocytic leukemia – M3*.
>
> Trisenox (arsenic trioxide) has been granted orphan-drug designation in each of these diseases, denoted by *** within Compendia-Based Drug Bulletin. As you are aware, the FDA only grants this status to drugs targeted for the treatment of rare disorders. It does so with the understanding that patients will be provided better access to treatment. HCFA and the FDA are collaborating to ensure that patients treated by orphan designated drugs will be afforded coverage, and hence more treatment options.
>
> **Generic Drug Index**
>
> Arsenic Trioxide (Trisenox)
>
> | | |
> |---|---|
> | Acute Promyelocytic Leukemia | 205.00, 205.01 |
> | Multiple Myeloma*** | 203.00, 203.01 |
> | Myelodysplastic Syndrome*** | 238.7 |
> | Chronic Myeloid Leukemia*** | 205.10, 205.11 |
>
> As per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item.

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> Therefore, we are requesting a formulary listing in your state/states.
>
> (emphasis in original).

179. This letter is misleading for several reasons. First, while Trisenox is indeed listed in USPDI, it is listed in Volume III as a result of being listed in the Orange Book. *See supra* ¶ 171. LASH's letter makes no distinction between Volume I, which lists medically accepted indications, and Volume III, which does not. This material omission created the grossly false impression that Trisenox was medically accepted and thus appropriate for Medicare coverage. Nor does it indicate, as the Relator's original letter did, that its listing in Volume III was "achieved listing through FDA approved Orphan Drug Designation." *See supra* ¶ 175.

180. The letter is further misleading because it creates the erroneous impression that orphan drug designation is associated with the affordability of treatments and that it was the intent of FDA and HCFA (the former federal agency governing Medicare, Medicaid, etc.) to provide coverage to those treatments that have such a designation. Stated another way, because Trisenox **only** had orphan drug status in these listed off-label uses, Congress must have intended for it to be covered by Medicare. The authority governing orphan drug exclusivity is found in the Orphan Drug Statute. 21 U.S.C. §§ 360aa-dd. Its intent is to promote the development of drugs for those rare diseases that strike a limited population. The statute does this by granting drug manufacturers an exclusivity period of 7 years and other financial incentives. 21 U.S.C. § 360cc. Thus, the Orphan Drug Act seeks to simply make the drug **available** for patients, which is wholly independent from making it affordable for them.

181. LASH's letter still further distorts the picture by using a broad act in the Medicare Cancer Coverage Act of 1994 as a proffer of authority for the position that orphan drugs are automatically reimbursed, rather than citing specific regulatory provisions. As CTI's

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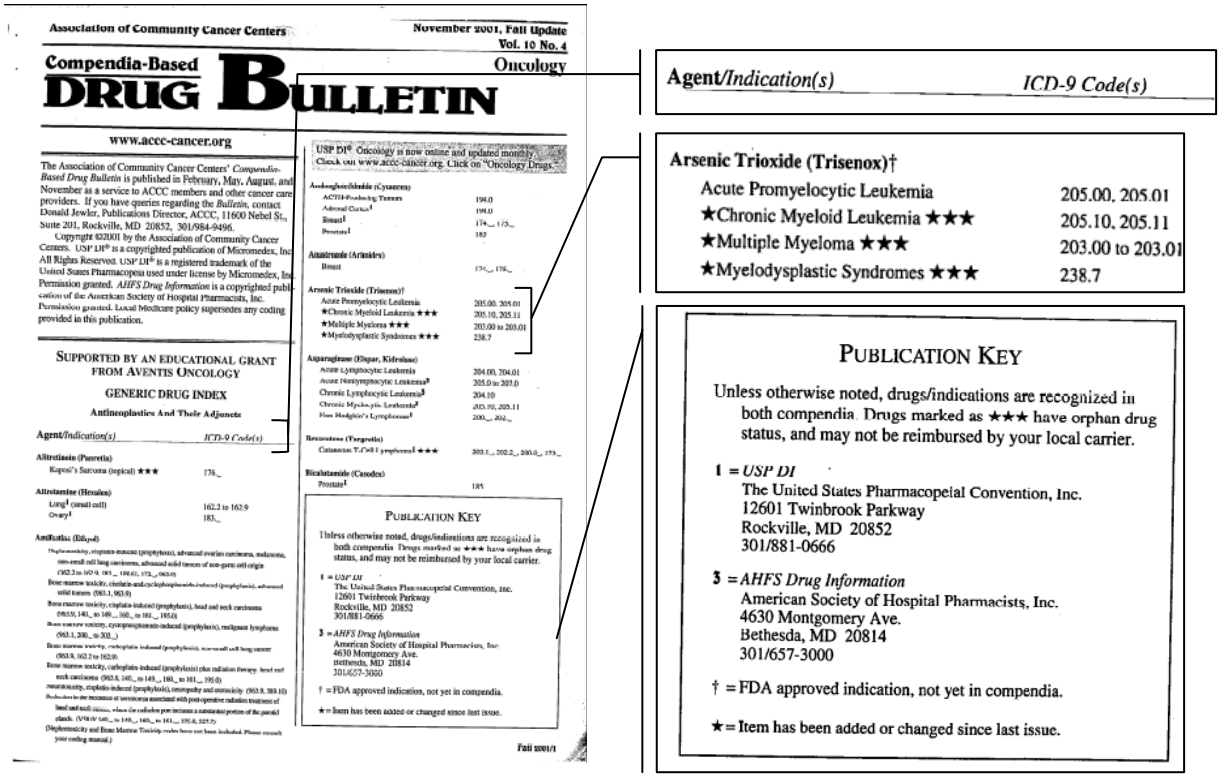
reimbursement services expert, who kept abreast of Medicare regulations and payment policies, LASH knew or acted in reckless disregard of the facts set forth herein when rendering its advice, resulting in LASH's artful drafting of the letter described above. Thus, LASH knew that its advice would cause CTI to induce physicians and/or their patients into submitting false claims to Medicare and the other Government-funded health insurance programs for reimbursement of Trisenox.

182. The ACCC publication actually lists Trisenox as follows:



Association of Community Cancer Centers — November 2001, Fall Update, Vol. 10 No. 4

Compendia-Based DRUG BULLETIN Oncology

www.accc-cancer.org

SUPPORTED BY AN EDUCATIONAL GRANT FROM AVENTIS ONCOLOGY

GENERIC DRUG INDEX

Antineoplastics And Their Adjuncts

Agent/*Indication(s)* — *ICD-9 Code(s)*

Arsenic Trioxide (Trisenox)†

Acute Promyelocytic Leukemia	205.00, 205.01
★Chronic Myeloid Leukemia ★★★	205.10, 205.11
★Multiple Myeloma ★★★	203.00 to 203.01
★Myelodysplastic Syndromes ★★★	238.7

PUBLICATION KEY

Unless otherwise noted, drugs/indications are recognized in both compendia. Drugs marked as ★★★ have orphan drug status, and may not be reimbursed by your local carrier.

1 = *USP DI*
The United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852
301/881-0666

3 = *AHFS Drug Information*
American Society of Hospital Pharmacists, Inc.
4630 Montgomery Ave.
Bethesda, MD 20814
301/657-3000

† = FDA approved indication, not yet in compendia.

★ = Item has been added or changed since last issue.

183. Still yet another material difference between LASH's letter and the ACCC publication is that the ACCC publication denotes by the symbol "†" that Trisenox does have an "FDA approved indication," but is "not yet in compendia." LASH's letter omits the "†" symbol because LASH knew that keeping it in would clearly point out that Trisenox was not yet listed as "accepted" in any FDA-recognized Compendia (*i.e.*, USPDI-Volume I) and would alert

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Medicare carriers to the fact that Trisenox was not entitled to automatic reimbursement as implied by its letter. In fact, the Drug Information monograph for Trisenox was not listed in USPDI-Volume I until the 2002 Edition was released during the first-quarter of that year, only receiving an "accepted" indication for APL. Not only was the "†" symbol omitted, but LASH's version of the letter leaves out the most important statement in the entire bulletin, "Drugs marked as *** have orphan drug status and **may not** be reimbursed by your local carrier." (*See* ¶ 182, emphasis added.)

184. Relator intended to send out FDA letters granting orphan designation, but LASH preferred to create ambiguity by sending the ACCC bulletin. At all times, Relator believed only – and correctly – that achieving an orphan drug designation was sufficient for a listing in the FDA-recognized Compendia. LASH, by contrast, knew that orphan drug designation was not sufficient for a *medically accepted* indication in the Compendia. Accordingly, LASH avoided sending the FDA letters, and instead used an advertising bulletin as proof of medical acceptance in off-label uses of Trisenox.

(3) CTI's and LASH's Secondary Efforts to Convince Medicare Carriers to Reimburse Off-Label.

185. Convincing Medicare and other Government-funded health insurance programs into believing that Trisenox was medically accepted for its off-label uses was only half the battle. The other half was convincing physicians to prescribe Trisenox off-label and to get patients enrolled in the reimbursement program.

186. LASH was paid as an independent company to administer the reimbursement program on behalf of CTI, and did so through a multi-step process. First, LASH confirmed that the patient had a physician prescription for Trisenox. LASH then registered the patient into the program by gathering information concerning the patient and his/her insurance coverage,

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entering this information into a CTI database. Thereafter, LASH conducted a limited medical coverage review to ensure that the patient fell within the medical necessity parameters for Trisenox. LASH submitted necessary information to the applicable insurer and attempted to obtain pre-authorization for the drug's use. Where the patient had insurance coverage for Trisenox, LASH would inform the patient and the treating physician of the parameters of the insurance coverage. Where a patient/provider would call seeking assistance with a rejected claim, LASH would prepare the claim and move it along the appeals process.

187. At no time was Relator, or anyone at CTI, involved in this process, nor did any of CTI's personnel provide input or documentation throughout. In fact, Relator Marchese never physically visited LASH's corporate offices, nor did he ever have a face-to-face meeting with any LASH representatives after it had been decided how CTI was going to pursue Trisenox reimbursement off-label. Relator was only provided periodic reports through Sean Gilbertson, Director of Operations, showing LASH's success rates in their appeals process with each of the state Medicare medical review boards, a review process that demonstrates their intimate knowledge of the drug's true status -- medically or not-medically accepted; approved and unapproved off-label uses. LASH would utilize non-peer-reviewed, non-published, and non-IND approved or FDA-reviewed studies, all of which are universally acknowledged as the gold standard of the medical industry. During these appeals, LASH sat in front of a medical physician with mere abstracts and an advertising bulletin in an attempt to convince them that the use was medically accepted.

188. When contacting the providers and/or physicians, LASH personnel followed a script that it developed as part of its services to CTI. Once word got out to the oncology community that Trisenox was apparently listed in the authoritative Compendia and thus was

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receiving insurance coverage (including Medicare), the scripts were revamped to tout this errant fact. Relator Marchese learned that these revamped scripts deliberately withheld the fact of whether or not a particular off-label use had not been "medically accepted." Thus, when contacting physicians and/or patients regarding Trisenox off-label, LASH would simply explain that because Trisenox was compendia listed, it was Medicare's policy to cover it. Yet, it was LASH's legal obligation to explicitly disclose when a particular use of a drug is for an unapproved use. *See* 21 U.S.C. § 360aaa, *see supra* ¶ 43.

189. When a claim for off-label use was denied, LASH took the opportunity while handling the appeal to persuade any particular Medicare carrier into believing that Trisenox use off-label was "medically accepted" because it was compendia-listed as an orphan drug, and because compendia-listed drugs are normally afforded Medicare coverage. This is the same message it sought to relay in its November letter to the Medicare Medical Directors. Only now, LASH had direct contact with the Medicare carrier, who ultimately made the final "medical acceptance" determination described above, and without any input from either CTI or Relator Marchese. They were successful on numerous occasions.

190. Typically, LASH would discuss denied claims over the phone with the particular Medicare review board. But LASH would not lightly take "no" for an answer. Indeed, on at least one occasion, LASH personally appeared in front of the review boards of TrailBlazer Health Enterprises, one of the largest Medicare contractors in the country, and convinced these reviewers that Trisenox was reimbursable for off-label uses because of its orphan drug designation. Notably, one or more of these meetings took place AFTER Marchese had already left the company in September 2002.

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191. As this reimbursement scheme began to gain traction among the state Medicare carriers, sales in Trisenox increased dramatically. Indeed, within six months, Medicare reimbursement for off-label use became the main driver of Trisenox sales. CTI's public filings show that for the six-months ending June 30, 2002, net U.S. sales of Trisenox had already reached nearly two-thirds of the total net sales from 2001. Total net sales for 2002 nearly increased 100% versus 2001, with nearly 90% of this sales growth tied to off-label uses.

192. LASH used "surveillance" reports that contained Trisenox usage data that allowed LASH to track the number of appeal "wins" and the geographic locations where these occurred so that CTI could target its sales force to those regions. In addition, the patient information data that LASH collected during enrollment into the reimbursement program and used for pre-authorization submissions served to quickly prepare denied claims for appeal. LASH's data informed CTI sales representatives which states were providing coverage, the number of appeal wins in those regions, and which treatment codes (CPT-4 or ICD-9-CM) were being covered. From this, CTI's sales force was given a roadmap of where they could successfully market Trisenox for off-label use.

193. As Trisenox became nationally recognized, LASH and Gilbertson eliminated Relator Marchese completely from being copied on any documents or receiving any information, and Marchese was even demoted so that he could have no contact with the reimbursement program. The marketing data provided by LASH was presented during 1-2 hour break-out sessions by Shawn Gilbertson during CTI's National Sales Meetings, in which LASH representatives were in attendance. Marchese played no part in these presentations.

194. LASH's compensation from CTI was directly dependent on the success of Defendants' off-label marketing scheme in that LASH's fees were based, in-part, on the number

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of occasions it handled insurance verification and eligibility, and also appeals. Thus, LASH had its own perverse incentive to increase the number of patients and physicians enrolled in its program.

COUNT I

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)

195. Relator re-alleges and incorporates by reference each and every paragraph previously alleged.

196. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1).

197. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to Medicaid and other Government-funded health insurance programs false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Trisenox.

198. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused to be presented, paid for claims that otherwise would not have been allowed.

199. By reason of these payments, the United States has been damaged in substantial amounts.

COUNT II

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

200. Relator re-alleges and incorporates by reference each and every paragraph previously alleged.

201. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(2).

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202. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly caused to be made or used false records or statements that caused false claims to be paid or approved by the United States Government.

203. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

204. By reason of these payments, the United States has been damaged in substantial amounts.

COUNT III

Federal False Claims Act, 31 U.S.C. § 3729(a)(3)

205. Relator re-alleges and incorporates by reference each and every paragraph previously alleged.

206. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(3).

207. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to defraud the United States Government by causing false or fraudulent claims for medical prescriptions to be allowed or to be paid or approved by the United States Government.

208. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

209. By reason of these payments, the United States has been damaged in substantial amounts.

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COUNT IV

Federal False Claims Act, 31 U.S.C. § 3730(h)

210. Relator re-alleges and incorporates by reference each and every paragraph previously alleged.

211. Defendants harassed, threatened, and discriminated against Relator because of his actions protected under the terms of 31 U.S.C. §3730(h). Said proscribed discrimination included but was not limited to demoting and eventually discharging Relator from employment.

WHEREFORE, Relator James Marchese requests that judgment be entered against Defendants, ordering that:

1. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729-33;

2. Defendants pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions;

3. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d);

4. Relator be awarded reimbursement for all costs of this action, including attorneys' fees and expenses pursuant to 31 U.S.C. § 3730(d);

5. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

6. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

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7. Relator be compensated for harm suffered as a result of Defendants' violation of 31 U.S.C. § 3730(h) and awarded all relief provided by that statute; and

8. The United States and Relator James Marchese recover such other relief as the Court deems just and proper.

V. REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator James Marchese hereby requests a trial by jury.

Respectfully submitted this 24th day of August, 2007.

McKAY CHADWELL, PLLC

s/ *Robert G. Chadwell*
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