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Judge Pechman

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06-CV-00168-CMP

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, ex rel. JAMES MARCHESE,

Plaintiff,

v.

CELL THERAPEUTICS, INC.,

Defendant.

NO. C-06-0168-MJP

**UNITED STATES' COMPLAINT IN INTERVENTION**

The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover all available damages and other monetary relief under the common law or equitable theories of fraud, negligent misrepresentation and unjust enrichment. The allegations contained in this complaint supercede relator James Marchese's complaint to the extent the allegations are set forth below.

## I. INTRODUCTION

1. This case involves a scheme by defendant Cell Therapeutics, Inc. ("CTI"), to market and promote its drug Trisenox (Arsenic Trioxide), a form of the common household poison arsenic, for the off-label treatment of various forms of cancer, when CTI knew that the use of the drug for such cancers was not medically accepted, and had not been found by the Food and Drug Administration (the "FDA") to be safe and effective.



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2. In the course of its off-label marketing scheme, CTI made false and misleading statements to treating doctors to the effect that Trisenox was medically accepted for the off-label uses being promoted, and therefore eligible for Medicare reimbursement. In reliance on CTI's false statements, treating physicians mistakenly administered Trisenox to their patients. CTI thus caused physicians to present false claims for payment to Medicare. Furthermore, CTI also caused a series of separate false statements to be made to medical directors working for Medicare program carriers to try to obtain Medicare reimbursement for off-label uses of Trisenox, when CTI knew that Trisenox had not been found to be safe and effective by the FDA, and was not medically accepted for such uses. CTI's false statements regarding the off-label indications of its drug caused the Trisenox to be "misbranded" as that term is defined by Title 21, United States Code, Section 353(f), and the shipment of that misbranded Trisenox in interstate commerce constituted a violation of Title 21, United States Code, Section 331(a). Likewise, it caused the Trisenox to be an unapproved new drug pursuant to Title 21, United States Code, Section 355, and its shipment in interstate commerce violated Title 21, United States Code, Section 331(d). Additionally, CTI's false statements led to the submission of and payment for false claims by the Medicare program, which violated Section 3729(a)(1) and (a)(2) of the FCA.

3. In conjunction with its off-label marketing scheme, CTI provided doctors and others with money, free travel, food and entertainment, grants, and other valuable goods and services, with the intent to induce physicians to prescribe Trisenox for unapproved indications. This conduct violated the Medicare-Medicaid Anti-Kickback Act ("AKS"), 42 U.S.C. § 1320a-7b(b). Because CTI's conduct caused physicians to submit false claims to the Medicare program for non-covered uses of Trisenox, CTI also violated Section 3729(a)(1) of the FCA.



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4. Finally, CTI paid thousands of dollars to treating physicians ostensibly to conduct research on the off-label uses of Trisenox, although such payments were unconnected with CTI's actual research department. To wrongfully promote off-label uses of Trisenox in violation of the FDCA, CTI required physicians conducting such studies to purchase Trisenox from commercial sources, instead of providing the study drug to them at no cost or at CTI's production cost, as required by law, knowing that such physicians would never agree to purchase Trisenox if they could not then pass these costs through to Medicare and other third party payers. When physicians expressed concern over the risk of non-payment for such non-covered uses of Trisenox, CTI promised to hold the physicians harmless by providing free "drug replacement" in the event their claims were denied, but only if the physicians first unsuccessfully attempted to bill third party payers such as Medicare. Since CTI knew that Trisenox was not covered by Medicare for its off-label uses, CTI's drug replacement program *in combination with its improperly run clinical studies*, caused such physicians to submit what CTI knew would be non-covered claims to Medicare in violation of Section 3729(a)(1) of the FCA.

5. As the direct, proximate and foreseeable result of CTI's false and fraudulent conduct, set forth above, CTI (a) caused physicians unwittingly to submit tens of thousands of false claims to the Medicare program seeking reimbursement for Trisenox prescriptions which CTI knew were not medically accepted and therefore ineligible for Medicare reimbursement; and (b) used false or fraudulent statements to get the Medicare program to reimburse millions of dollars of false and fraudulent claims submitted by the physicians. CTI's illegal scheme to promote the prescription of Trisenox for indications which were neither FDA approved nor medically accepted, greatly increased Trisenox sales to the financial benefit of CTI, but caused the Medicare Program to pay millions of dollars for the administration of a drug with no proven medical value to thousands of persons who were dying of cancer.



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## II. JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, and 1345, and 31 U.S.C. § 3732.

7. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant's principal place of business is in the Western District of Washington. Additionally, this Court has personal jurisdiction over Defendant because acts prohibited by 31 U.S.C. § 3729 have occurred in this District. 31 U.S.C. § 3732(a).

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant can be found, resides and transacts business in this, the Western District of Washington and at least one act proscribed by 31 U.S.C. § 3729 occurred in this District.

## III. PARTIES

9. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), which is charged with administering the Medicare program through the Centers for Medicare and Medicaid Services ("CMS") formerly known as the Health Care Financing Administration.

10. Relator, James Marchese, is a resident of New Jersey and a former employee of defendant Cell Therapeutics, Inc. On February 1, 2006, Mr. Marchese filed an action alleging violations of the False Claims Act, 31 U.S.C. §§ 3729 et seq., on behalf of himself and the United States Government pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b)(1).



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11. Defendant CTI is a corporation with its principal place of business located at 501 Elliott Avenue West, Seattle, Washington. CTI is principally engaged in the development, manufacture and sale of pharmaceuticals, including prescription pharmaceuticals subject to regulation by the FDA. From 2000 until 2005, CTI, owned, manufactured, and sold the prescription drug Trisenox.

## IV. ALLEGATIONS

### A. *CTI's Off-Label Promotion of Trisenox*

12. The FDCA (21 U.S.C. §§ 301-99) governs, among other things, the testing, approval, manufacture, labeling and distribution in interstate commerce of prescription medicines. Under the FDCA a "new drug" means any drug the composition of which is such that the drug is not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321 (p)(1). "New drugs" cannot be distributed in interstate commerce unless the person who seeks to distribute the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses, and there is in effect for such drug an approval of a new drug application (NDA) pursuant to 21 U.S.C. § 355(b), or an abbreviated new drug application (ANDA) pursuant to 21 U.S.C. § 355(j), or an investigational new drug (IND) submission pursuant to 21 U.S.C. § 3555(i). See 21 U.S.C. §§ 355(a), (d), 331(d). While physicians may prescribe approved drugs for off-label uses, drug manufacturers are prohibited from marketing or promoting a drug for a use that FDA has not approved.

13. A drug is misbranded under the FDCA if, among other things: its labeling is false or misleading in any particular, see 21 U.S.C. § 352(a); the labeling on the drug does not bear adequate directions for use, see 21 U.S.C. § 352(f)(1); and the labeling on the drug does not bear such adequate warnings against use in those pathological conditions, and by children where its use may be dangerous to health, and against unsafe dosage and methods and



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duration of administration and application, in such manner and form, as necessary for the protection of users. See 21 U.S.C. § 352(f)(2). The FDCA also prohibits the distribution in interstate commerce of misbranded drugs. See 21 U.S.C. § 331(a) (prohibiting the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of any drug that is misbranded); 21 U.S.C. § 331(c) (prohibiting the receipt in interstate commerce, or causing the receipt in interstate commerce of any drug that is misbranded, and the delivery or proffered delivery thereof for pay or otherwise); and 21 U.S.C. § 331(k) (prohibiting the doing of any act, or causing any act to be done with respect to a drug if such act results in the drug being misbranded).

14. "Adequate directions for use" is defined by regulation to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended." See 21 C.F.R. § 201.5. The "intended use" of a drug refers "to the objective intent of the persons legally responsible for the labeling of drugs." See 21 C.F.R. § 201.128. "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article[,]" and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." Id.

15 On September 25, 2000, the FDA approved an NDA for Trisenox for the treatment of acute promyelocytic leukemia (APL) – a specific and rare type of leukemia that affects only 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. The FDA approved the NDA



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for Trisenox *only* for APL in patients who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, the standard first-line treatment for APL. Trisenox has never been approved by the FDA for the treatment of any other diseases.

16. As of the date of the filing of this complaint, Trisenox is the only drug for which CTI has ever obtained marketing approval from the FDA. The sole use for which CTI's NDA for Trisenox was approved by FDA was the treatment of relapsed APL.

17. The FDA approval of a drug is limited to the specific indications for use listed in the NDA, and the manufacturer may only market the drug for those specific indications. Within the body of the approved NDA (which may consist of volumes of material) is the exact labeling which the manufacturer is required to provide with the drug, and is based on the approved indications for use. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all other written, printed, or graphic material, "(1) upon [the drug] or any of its containers or wrappers, or (2) accompanying such [drug]." 21 U.S.C. § 321(m). FDA reviews the proposed labeling under 21 U.S.C. § 355(b)(1)(F), because such labeling contains the claims that the drug's manufacturer or sponsor intend to make for its use.

18. Because a drug approval is limited to those specific uses listed in the NDA, if a manufacturer promotes an approved drug for an indication not in the NDA, it is not covered by the approval, and is therefore an unapproved new drug as to that use. Likewise, if "labeling" for the drug suggests indications for use that are not in the NDA, the drug lacks adequate directions for that use, and the drug is misbranded pursuant to 21 U.S.C. §352(f).

19. On the other hand, a licensed physician may prescribe most approved drugs for any purpose that he or she deems medically appropriate, regardless of whether the drug has been approved for that use by the FDA, so long as the use is considered within the reasonable



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practice of medicine under state law. Prescribing drugs for unapproved, but medically accepted, uses is commonplace in modern medical practice, particularly in oncology. While it is not *per se* illegal for a manufacturer to provide physicians with information concerning off-label uses of a drug, stringent legal requirements apply to any such communications. 21 U.S.C. § 360aaa, et seq.

20. Medicare is a federal health insurance program for people aged 65 and older as well as persons under 65 who are blind or disabled. As set forth above, the Medicare program is administered by CMS, a division of HHS. CMS contracts with private companies to process and pay claims submitted by Medicare providers for the treatment of Medicare beneficiaries. Those private companies who process Medicare claims submitted by physicians are called "Medicare Carriers;" those who process Medicare claims submitted by hospitals are called "Medicare Intermediaries."

21. During the time period covered by this Complaint, Medicare provided limited benefits for outpatient drugs. Specifically, Medicare paid for anti-cancer drugs in an out-patient context only if the drug was prescribed for an indication or use for which the drug had been specifically approved by the FDA, or the drug was prescribed for a "medically accepted indication" which was defined as a use of the drug that was supported by one or more citations in certain specified drug compendia published by third parties, see 42 U.S.C. § 1395x(t)(2)(B)(ii)(I), or by "clinical evidence in peer reviewed medical literature appearing in publications which have been identified ... by the Secretary." 42 U.S.C. § 1395x(t)(2)(B)(ii)(II).

22. At all times relevant hereto, the Medicare Benefit Policy Manual (the "Manual") provided additional guidance with regard to Medicare reimbursement for non-FDA-approved uses of anti-cancer drugs. The Manual provided that Medicare would reimburse for off-label prescriptions where the off-label use was supported in the text of at least one of three specific



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drug compendia or one of fifteen specific peer-reviewed medical journals. See Manual at § 50.4.5. Of the three compendia identified in the Manual, only two compendia were still in publication during the period relevant to this case: the United States Pharmacopoeia Drug Information (USP-DI) and American Society of Health-System Pharmacists (AHFS).

23. At all times relevant hereto, the Manual provided with respect to the USP-DI that: "Indications for use appear as accepted, unaccepted, or insufficient data. An indication is considered to be a medically accepted use only if the indication is listed as accepted." See Manual at § 50.4.5(C). Thus to be eligible for reimbursement when prescribed off-label, an anti-cancer drug's use must be "listed as accepted" in the USP-DI.

24. The Orphan Drug Act (ODA), 21 U.S.C. §§ 360aa-360dd, provides incentives to drug manufacturers to research treatment for diseases and medical conditions that effect a relatively small number of people in the United States, generally under 200,000 individuals.

25. Under the ODA, the FDA is required to grant orphan drug designation if the sponsor shows a "medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition." 21 C.F.R. § 316.25(a)(2).

26. The fact that a drug has been designated as an orphan drug under the ODA does not mean that the drug is FDA approved for the treatment of that indication; it does not mean that the drug is medically accepted for the treatment of the indication; and the fact that a drug has received orphan designation for a disease has no relevance at all with respect to the question of Medicare reimbursement.

27. Beginning in 2001, CTI wished to find ways to increase sales of Trisenox by marketing Trisenox for the treatment of diseases other than APL which, due to its rarity, limited the legitimate market for Trisenox. CTI initially hoped to market Trisenox for



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Multiple Myeloma (MM), a type of cancer which is diagnosed in over 50,000 patients, with 15,000 new cases per year; and for Myelodysplastic Syndromes (MDS), a type of cancer which is diagnosed in 36,000 patients, with 15,000 new cases per year. Ultimately, CTI would seek to market Trisenox for chronic myeloid leukemia ("CML"), for chronic lymphocytic leukemia ("CLL"), for various types of liver cancer and for various subtypes of AML (other than APL).

28. MM, MDS, CML, CLL, liver cancer and AML are all separate and distinct diseases from APL, 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 only after appropriate clinical trials demonstrating a drug's efficacy and safety for the treatment of each disease. Tisenox was not approved by the FDA for any indication other than APL.

29. CTI recognized that it could not successfully sell Trisenox for MM, MDS, CML, CLL, liver cancer or AML unless it convinced oncologists to prescribe Trisenox for these off-label indications. CTI also recognized that it was unlikely that oncologists would prescribe Trisenox for MM, MDS, CML, CLL, liver cancer or AML unless oncologists were convinced that Trisenox was a medically accepted indication for those diseases and thus their prescriptions would be eligible to be reimbursed by the Medicare program. CTI also recognized that it would have to convince the Medical Directors of the Medicare Carriers that Trisenox was a medically accepted indication for MM, MDS, CML, CLL, liver cancer and AML in order for Medicare to reimburse the off-label prescriptions as a matter of routine and thus perpetuate the cycle of prescriptions by oncologists.

30. Because of the lack of peer-reviewed literature supporting the medical acceptance of the use of Trisenox "off-label," Trisenox has never been listed as medically accepted for



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any off-label indication in either of the two Medicare approved drug compendia, i.e. USP-DI or AHFS.

31. In September, 2001, CTI employees set in motion a plan to convince oncologists and the Medical Directors of the Medicare Carriers that various off-label uses of Trisenox were eligible for Medicare reimbursement. The plan took advantage of the fact that the USP-DI contained a section dealing with orphan drug designations. This section of the USP-DI contained a list of drugs arranged alphabetically by their generic names and showed any orphan drug designation(s) the drug has obtained from the FDA, the date of the orphan drug designation and, if applicable, the date that the drug received marketing approval for the orphan drug designation. The list of orphan drugs in the USP-DI was separate and apart from and in no way relevant to the question of the medical acceptance of the drug for any particular treatment or indication. High level CTI employees had actual knowledge of the fact that receiving an orphan designation for a drug had nothing to do with the question of medical acceptance of a drug for purposes of treatment, and other CTI employees acted in reckless disregard of this fact.

32. In order to determine whether a drug is listed as medically accepted for an indication in the compendia and therefore reimbursable, many oncologists, who do not themselves own a copy of the two compendia described in paragraph 22, rely instead on a publication called the Compendia Based Drug Bulletin (the "Bulletin"). The Bulletin is published by the Association of Community Cancer Centers (the "ACCC"). The Bulletin operates as a kind of "Cliff's Notes" for the two Compendia. Copies of the Bulletin are provided free of charge to any oncologist who requests to be included on the ACCC's mailing list, and the Bulletin is also available on-line at the ACCC's web-site (www.accc-cancer.org).



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33. Because of its easy to read, convenient format, the Bulletin is extensively relied on by oncologists as an authoritative source for most of their questions about reimbursement, particularly Medicare reimbursement. For the same reasons, the doctors who serve as Medicare Medical Directors also rely on the Bulletin.

34. In the Fall of 2001, CTI contacted the ACCC about getting the off-label orphan drug indications for Trisenox listed in the Bulletin – *even though there was no peer reviewed medical literature indicating that the drug was medically effective for those indications and the drug was not listed as medically accepted in either of the two compendia.* In September of 2001, James Marchese, a CTI employee, talked to Don Jeweler, the director of communications for the ACCC. Marchese agreed on behalf of CTI to give ACCC an "educational grant" of $10,000 per year. In exchange, Jeweler agreed on behalf of ACCC to place a banner ad for CTI in a high traffic area on the ACCC website, to list Trisenox's orphan drug designations in the Bulletin, and to ship 3000 copies of the next three issues of the Bulletin to CTI.

35. In a letter dated September 20, 2001, Jeweler described the objective of ACCC's agreement with CTI as follows:

> To raise awareness among oncology health care professionals about Cell Therapeutics, Inc. and Trisenox (including its orphan drug designation for the treatment of MDS, multiple myeloma and APL).

36. On October 16, 2001, CEO James Bianco sent Marchese the following email message:

> I heard from Mark and Peter that you may have worked your magic again with a potential way to get us listed for our orphan designations in the Compendia well ahead of the end of 2002 target through the more traditional route. If this proves effective, it would be a major accomplishment for your team. Nice work – I'll keep my fingers crossed. Jim



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37. In the November 2001, Fall Update, Vol. 10 No. 4, issue of the Bulletin, Trisenox appeared as set forth below:

| **Agent**/*Indication(s)* | *ICD-9 Code(s)* |
|---|---|
| * * * | |
| **Aresenic Trioxide (Trisenox)†** | |
| Acute Promyelocytic Leukemia | 205.00, 205.01 |
| ★Chronic Myeloid Leukemia★★★ | 205.10, 205.11 |
| ★Multiple Myeloma★★★ | 203.00 to 203.01 |
| ★Myelodysplatic 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*

***

3 = *AHFS Drug Information*

***

† = FDA approved indication, not yet in compendia.

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

38. The November 2001, Vol. 10 No. 4, issue of the Bulletin was false and misleading because it included a symbol (†) next to Trisenox, which according to the Publication Key, indicated that each subsequently listed indication for Trisenox was a, "FDA approved indication, not yet in compendia." This was false and misleading because CML, MM and MDS were not FDA-approved indications for Trisenox. The Bulletin entry for Trisenox was also false and misleading because it appeared to state that each listed indication for Trisenox was "recognized in both compendia" implying that such uses were medically accepted. In fact, Trisenox was not a "recognized" treatment in either of the compendia for CML, MM or MDS. Indeed, Trisenox was only mentioned in the USP DI as having been designated as an orphan drug for MM.



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39. As part of its $10,000 deal with the ACCC, CTI received 3000 copies of the false and misleading November 2001, Vol. 10 No. 4, issue of Bulletin from the ACCC. These copies were distributed to all of CTI's salespeople, who were given express written instructions to leave copies with every potential account they visited. On information and belief, all or virtually all copies of the 3000 false and misleading November 2001, Vol. 10 No. 4, issues of the Bulletin that CTI received were distributed to physicians and their medical staff by CTI salespeople. CTI salespeople were trained as follows:

> Q. What is Compendia and why is it important?
>
> A. Compendia literally refers to any text book used by medical professionals to determine treatment options for a given disease. The USP-DI and AHFS are the only government recognized books that establish acceptable treatment patterns. The legislature uses "Compendia listed" to describe these books and therefore these 2 book sets determine what is a reimburseable pratices [sic] in medicine.
>
> Q. What is the ACCC and how does it get involved with Compendia?
>
> A. The ACCC is one of the most respected and largest cancer focused organization in the country. It facilitates community cancer center practices. The ACCC reviews the USP-DI and AHFS and puts out a footnotes [sic] called the *Compendia Bulletin. This bulletin is relied upon by carriers* and community practices to determine reimburseable treatments. (The actual USP-DI and AHFS are volumes of medical text containing 1000's of pages that would be impossible for office managers and carriers to follow, so the ACCC put together cliff notes.)

40. At the times it distributed the November 2001, Vol. 10 No. 4, issues of the Bulletin to physicians, CTI knew that the FDA had not approved Trisenox for CML, MM and MDS but did not inform the physicians to whom it distributed the Bulletin of this fact. CTI also knew that CML, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact. CTI also knew that Trisenox was not reimburseable by Medicare when prescribed off-label for CML, MM and MDS, but did not inform physicians or their staff of this fact. However, as set forth in paragraph 39 above, CTI's sales people were trained to use the Bulletin to mislead



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physicians and their medical staff into believing that off-label uses of Trisenox were medically accepted and reimburseable by Medicare.

41. On November 27, 2001, upon receipt of the 3000 copies of the November 2001 issue of the Bulletin, Peter Sportelli, the head of CTI's sales force, wrote the following email message to Marchese:

> It does look beautiful – we were all admiring the bulletin in the office yesterday. Outstanding job Jim – I never underestimate your capacities. Now for the test over the first few months – you are absolutely correct, even if it works in one state, it's a HUGE win! And it will at least drive new patient starts, with the understanding that no reimbursement is ever guaranteed. If you keep a close eye on the reimbursement, that would be great – maybe look to have a report by end of Dec on any successes or denials that continue. Getting rich is a very good thing and it can't happen soon enough!

42. As part of its $10,000 deal with the ACCC, CTI received 3000 copies of the February 2002, Vol. 11 No. 1, issue of the Bulletin. The listing for Trisenox in this issue of the Bulletin was identical to the November 2001, Vol. 10 No. 4, issue described in paragraph 37, above, and was false and misleading for the same reasons set forth in paragraph 38, above. On information and belief, all or nearly all of the 3000 false and misleading February 2002, Vol. 11 No. 1, issues were distributed to physicians by CTI salespeople.

43. At the times it distributed the February 2002, Vol. 11 No. 1, issues of the Bulletin to physicians, CTI knew that the FDA had not approved Trisenox for CML, MM and MDS but did not inform the physicians to whom it distributed the Bulletin of this fact. CTI also knew that CML, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact. CTI also knew that Trisenox was neither medically accepted nor reimburseable by Medicare when prescribed off-label for CML, MM and MDS; however, CTI used the Bulletin to mislead physicians into mistakenly believing that off-label Trisenox prescriptions were medically accepted and reimburseable.



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44. As part of its $10,000 deal with the ACCC, CTI received 3000 copies of the May 2002 Bulletin, Vol. 11 No. 2. The entry for Trisenox for this issue stated as follows:

| **Agent**/*Indication(s)* | *ICD-9 Code(s)* |
|---|---|
| *** | |
| **Arsenic Trioxide (Trisenox)** | |
| ★Acute Myelocytic Leukemia★★★ | |
| Acute Promyelocytic Leukemia | 205.00, 205.01 |
| Chronic Myeloid Leukemia★★★ | 205.10, 205.11 |
| Multiple Myeloma★★★ | 203.00 to 203.01 |
| Myelodysplatic 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*

***

3 = *AHFS Drug Information*

***

† = FDA approved indication, not yet in compendia.

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

45. The May 2002, Vol. 11 No. 2, issue of the Bulletin was false and misleading because it stated that each listed indication for Trisenox was "recognized in both compendia," implying that such uses were medically accepted. In fact, Trisenox was not "recognized" in either of the compendia for AML, CML, MM or MDS but was merely listed in the USP-DI as having been designated as an orphan drug for MM.

46. On information and belief, all or virtually all copies of the 3000 false and misleading May 2002, Vol. 11 No. 2, issues of the Bulletin that CTI received were distributed to physicians by CTI salespeople.



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47. At the times it distributed the November May 2002, Vol. 11 No. 2, issues of the Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML, MM and MDS. Moreover, CTI also knew that AML, CML, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact.

48. As part of its $10,000 deal with the ACCC, CTI received 3000 copies of the August 2002, Vol. 11 No. 3, issue of the Bulletin. The listing for Trisenox in this issue of the Bulletin was identical to the May 2002, Vol. 11 No. 2, issue described in paragraph 44, above, and was false and misleading for the same reasons set forth in paragraph 45 above. On information and belief, all or nearly all of the 3000 false and misleading August 2002, Vol. 11 No. 3, issues were distributed to physicians by CTI salespeople.

49. At the times it distributed copies of the August 2002, Vol. 11 No. 3, issue of the Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML, MM and MDS. CTI also knew that AML, CML, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact.

50. On information and belief, CTI made the following additional purchases of copies of the ACCC Bulletin: 3000 copies of the May 2003, Vol. 12 No. 2, issue. The listing for Trisenox in this issue of the Bulletin was identical to the May 2002, Vol. 11 No. 2, issue described in paragraph 44, above, and was false and misleading for the same reasons set forth in paragraph 45, above. On information and belief, all or nearly all of the 3000 false and



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misleading May 2003, Vol. 12 No. 2 issues were distributed to physicians by CTI salespeople.

51. At the times it distributed copies of the May 2003, Vol. 12 No. 2 issue of the Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML, MM and MDS. CTI also knew that AML, CML, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact.

52. On information and belief, CTI purchased 2400 copies of the August 2003, Vol. 12 No. 3, issue of the Bulletin. The entry for Trisenox in this issue stated:

| **Agent**/*Indication(s)* | *ICD-9 Code(s)* |
|---|---|
| *** | |
| **Arsenic Trioxide (Trisenox)** | |
| Acute Myelocytic Leukemia★★★ | 205.0 |
| Acute Promyelocytic Leukemia | 205.0 |
| ★Chronic Lymphocytic Leukemia | 204.1 |
| Chronic Myeloid Leukemia★★★ | 205.1 |
| ★ Liver★★★ | 155. |
| Multiple Myeloma★★★ | 203.0 |
| Myelodysplatic 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*
***
3 = *AHFS Drug Information*
***
† = FDA approved indication, not yet in compendia.
★ = Item has been added or changed since last issue.



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53. The August 2003, Vol. 12 No. 3, issue of the Bulletin was false and misleading because it stated that each listed indication for Trisenox was "recognized in both compendia," implying that such uses were medically accepted. In fact, Trisenox was not "recognized" as medically accepted in either of the compendia for AML, CML, CLL, Liver, MM or MDS but was merely listed as having been designated as an orphan drug for these indications.

54. On information and belief, all or nearly all of the 2400 false and misleading August 2003, Vol. 12 No. 3, issues were distributed to physicians by CTI salespeople.

55. At the times it distributed copies of the August 2003, Vol. 12 No. 3, issue of the Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML, MM and MDS. CTI also knew that AML, CML, CLL, Liver, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact.

56. On information and belief, CTI also purchased 5000 copies of the November 2003, Vol. 12 No. 4 issue; 500 copies of the May 2004, Vol. 13 No. 2, issue; 1000 copies of the August 2004, Vol. 13 No. 3, issue; 1000 copies of the February 2005, Vol. 14 No. 1, issue. The listing for Trisenox in these issues of the Bulletin were identical to the August 2003, Vol. 12 No. 3, issue described in paragraph 52, above, and was false and misleading for the same reasons set forth in paragraph 53 above. On information and belief, all or nearly all of these 7500 false and misleading copies of these Bulletins were distributed to physicians by CTI salespeople.

57. At the times it distributed the copies of the November 2003, Vol. 12 No. 4 issue, May 2004, Vol. 13 No. 2, issue; August 2004, Vol. 13 No. 3, issue; and February



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2005, Vol. 14 No. 1, issue of the Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML, MM and MDS. CTI also knew that AML, CML, CLL, Liver, MM and MDS were not recognized in the compendia as medically accepted indications for Trisenox, but CTI did not inform physicians of this fact.

58. In addition to providing copies of the false and misleading Bulletin to doctors, as described above, CTI salespeople routinely told the physicians with whom they met that because Trisenox's off-label uses were listed in the Bulletin, Trisenox had obtained Compendia listing. CTI intended that these statements would cause doctors to believe that the drug was medically accepted for the indications in question and hence was eligible for reimbursement thus leading doctors to prescribe Trisenox off-label and submit those off-label prescriptions to Medicare for reimbursement.

59. Physicians and other medical professionals relied on the false and misleading copies of the Bulletin which were provided to them by CTI salespeople and further relied on the false and misleading statements made by CTI salespeople to the effect that Trisenox had obtained Compendia listing. Because of CTI's misrepresentations, physicians and other medical professionals were misled into believing falsely that Trisenox was medically accepted for its off-label indications and prescribed Trisenox for their patients with these indications. These physicians also believed that Trisenox's off-label orphan-designated indications were eligible for Medicare reimbursement and submitted claims for payment to Medicare Carriers for Trisenox that was prescribed for off-label indications. On information and belief, among the physicians who were mislead by CTI's scheme to defraud were the following:[1] 1.Dr.JS, 1.Dr.LH, 1.Dr.KD, 1.Dr.FS, 1.Dr.BB, 1.Dr.SF, 1.Dr.ES, 1.Dr.RI, 1.Dr.JK, 1.Dr.RMcG,

[1] A complete and separate *Listing of Physicians Referencing this Complaint In Intervention* is being filed concurrently and Under Seal.



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1.Dr.MK, 1.Dr.SG, 1.Dr.JL, 1.Dr.RG, and 1.Dr.NG. CTI knew that physicians believed that Trisenox was medically accepted for its off-label indications and that they were purchasing the drug and administering it to their patients for these off-label indications, and CTI knew that physicians were billing Medicare for such non-covered prescriptions. All such off-label claims submitted by physicians to Medicare on or after November 2001 were false or fraudulent claims for purposes of the False Claims Act.

60. In November of 2001, CTI caused a company called Documedics (now the Lash Group, a division of Ameri-SourceBergen), which CTI had retained to assist it in obtaining Medicare reimbursement for off-label uses of Trisenox, to send a letter to the Medical Directors of all the Medicare Carriers. The letter was largely drafted by CTI's Shawn Gilbertson and James Marchese and CTI had ultimate authority over the contents of the letter and the decision to send the final version of the letter to the Medical Directors of the Medicare Carriers. CTI chose, however, to have the letter sent out by Documedics under the signature of a Documedics' employee for the express purpose of making the mailing appear as if it had come from an independent, disinterested third-party rather than from the actual manufacturer of the drug. In pertinent part, the November 2001 letter to the Medicare Medical Directors 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 [sic] 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. ... HCFA and the FDA are collaborating to ensure that patients treated by orphan designated drugs will be afforded coverage....
> ...
>
> As per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item. Therefore, we are requesting a formulary listing in your state/states.



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61. The November 2001 letter to the Medicare Medical Directors was false and misleading in at least four respects. First, the letter stated that the Bulletin, "detail[ed] diseases and therapies listed in the recognized Compendia (USP DI)." This was false and misleading because the orphan drug designations identified in the Bulletin and the USP-DI for Trisenox had not received marketing approval and were not deemed medically accepted and thus were not therapies for the diseases listed. Second, the letter stated that, "TRISENOX (arsenic trioxide) is newly listed in the Compendia for the following diseases [MM, MDS, CML and AML-M3]." This was false and misleading because it implied that Trisenox had received FDA-approval for or had been determined to be medically accepted for the diseases listed, which was not true for MM, MDS or CML; moreover Trisenox was not yet listed even as an orphan drug in the USP DI for CML. Third, the letter stated that "HCFA and the FDA are collaborating to ensure that patients treated by orphan designated drugs will be afforded coverage." This was false because coverage has nothing to do with orphan drug designation but rather depends on "medical acceptance" as defined in the two surviving drug compendia and 15 peer-reviewed journals. Fourth, the letter falsely represented that, "[a]s per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item." This was false because the MCA provides that a drug is covered for off-label indications not when it is "listed" but only if it is "medically accepted" where this term is defined as, "*supported* by one or more *citations* which are included (or approved for inclusion) in one or more of" the compendia. 42 U.S.C. § 1395x(t)(2)(B)(ii)(I) (emphasis added). Thus, the letter falsely suggested that carriers should be reimbursing Trisenox when prescribed and administered off-label for CML, MM and MDS.

62. As a result of the November 2001 letter to the Medicare Medical Directors, Medicare Carriers began routinely to approve claims for Trisenox when prescribed off-label for MM, MDS and CML. Empire Medicare Services, the Medicare Carrier for New Jersey and the county of Nassau in New York State, specifically acknowledged taking the step of approving off-label Trisenox as a result of receiving the November 2001 letter. On



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information and belief, other Medicare Carriers also took this step based on receipt of the November 2001 letter, including Nationwide Insurance, the Medicare Carrier for Ohio and West Virginia, and Noridian, the Medicare Carrier for Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington and Wyoming.

63. In February 2002, CTI decided to have Documedics send a second letter to those Medicare Carriers that had not yet responded affirmatively to the November 2001 letter described in paragraph 60, above. The February 2002 letter was again drafted in part and approved by CTI but again sent out under Documedics signature. The letter stated:

> As a consultant to cancer practices, I would like to take this opportunity to notify you of an update within the **USP DI, Volume III 2002.** 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 USP DI for the following diseases: *multiple myeloma, acute promyelocytic leukemia, in addition to the approved indication of acute myelocytic leukemia - M3.*
>
> ***
>
> HCFA and the FDA are collaborating to ensure that patients treated by orphan designated drugs will be afforded coverage, and hence more treatment options.
>
> **Orphan Drug Designation**
>
> Arsenic Trioxide (Trisenox) has been granted orphan drug designation in the following diseases:
>
> Chronic Myeloid Leukemia
> Multiple Myeloma
> Myelodysplastic syndrome (MDS)
> Acute Promyelocytic Leukemia (APL)
>
> As per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item. Therefore we are requesting a formulary listing in your state/states.

64. The February 2002 letter to the Medicare Medical Directors was false and misleading in at least four respects. First, the letter stated that an update to the "USP DI, Volume III 2002," "detail[ed] diseases and therapies listed in the recognized Compendia (USP DI)." This was false and misleading because the USP DI Volume III merely listed



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orphan drug designations for which Trisenox had not received marketing approval and thus those orphan drug designations were not deemed medically accepted and thus were not therapies for the diseases listed. Secondly, the letter stated that, "TRISENOX (arsenic trioxide) is newly listed in the Compendia for [MM]." This was false and misleading because it implied that Trisenox had received FDA-approval for or had been determined to be medically accepted for MM, which was not true. Third, the letter stated that "HCFA and the FDA are collaborating to ensure that patients treated by orphan designated drugs will be afforded coverage." This was false because coverage has nothing to do with orphan drug designation but rather depends on "medical acceptance" as defined in the two surviving drug compendia and 15 peer-reviewed journals. Fourth, the letter falsely represented that, "[a]s per the Medicare Cancer Coverage Act of 1994, a drug listed in one of the compendia should be a covered Medicare item." This was false because the MCA provides that a drug is covered for off-label indications not when it is "listed' but only if it is "medically accepted" where this term is defined as, "*supported* by one or more *citations* which are included (or approved for inclusion) in one or more of" the compendia. 42 U.S.C. § 1395x(t)(2)(B)(ii)(I) (emphasis added). Thus the letter falsely suggested that carriers should be reimbursing Trisenox when prescribed off-label for CML, MM and MDS.

65. As a result of the February 2002 letter to the Medicare Medical Directors, additional Medicare Carriers began routinely to approve claims for Trisenox when prescribed off-label for MM, MDS and CML, including Highmark Medicare Services, Inc., the Medicare carrier for Pennsylvania.

66. In March 2002, CTI enlisted the aid of 2.Dr.DMG of the San Antonio Blood and Tumor Clinic, who was also on the Board of Directors of TrailBlazer Health Enterprises, the Medicare Carrier for Texas, to help convince TrailBlazer to make off-label Trisenox prescriptions reimbursable by Medicare. CTI, with the aid of Documedics, drafted a letter for



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2.Dr.DMG's signature. 2.Dr.DMG, after making several edits to the draft, which were approved by CTI, sent the following to TrailBlazer on March 22, 2002:

> I am writing to notify you of an update within the 2002 USPDI, volume 3, regarding Trisenox injection. It has previously been listed for acute promyelocytic leukemia; however, newly listed indications now included multiple myeloma and myelodysplastic syndrome. It is anticipated that in the June USPDI, chronic myelogenous leukemia and acute myelogenous leukemia will also be included.
>
> Trisenox (arsenic trioxide) has been granted orphan-drug designation in each of the above diseases, and this grant by the FDA targets drugs to enhance the availability of treatment of rare diseases.
>
> In addition to having orphan-drug designation, several other Medicare carriers have issued positive coverage guidelines for all these diagnoses. These include a Noridian Carrier Bulletin that specifies coverage for off-label diagnoses that are compendia listed. Apparently Noridin [sic] has chosen not to publish individual, local, medical review policies because of the consistently growing list of approved indications for cancer drugs. Multiple myeloma, as a disease entity, has been cited for coverage by Empire, the carrier from New Jersey and part of New York, and also by Nationwide Insurance, the Medicare carrier for Ohio and West Virginia.
>
> With this information along with the information enclosed, I would urge you to consider coverage for use of Trisenox in the above-mentioned diseases. Please contact me if I can offer additional information.

67. The March 22 letter written on CTI's behalf was false and misleading. By stating that Trisenox had been "newly listed" in the USPDI for the indications of MM and MDS, the letter falsely suggested that these indications were medically accepted when in fact they were merely orphan drug designations. The letter was also false and misleading to the extent it referred to actions taken by Noridian, Empire and Nationwide Insurance to approve Trisenox prescription for the off-label indications since those approvals were obtained only through the fraudulent statements contained in the November 2001 letter which Documedics had sent to the Medicare Carriers at CTI's behest, which fact was not disclosed to Trailblazer.

68. On April 23, 2002, TrailBlazer's Medicare Medical Director wrote to 2.Dr.DMG acknowledging that based on the information sent by 2.Dr.DMG, TrailBlazer was adding the diagnoses of MM, MDS and CML to the covered indications for arsenic trioxide.



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69. The false and misleading statements in the November 2001 and February 2002 letters sent out at CTI's behest by Documedics to the Medicare Carriers and the false and misleading statements in the March 22, 2002 letter sent out at CTI's behest by 2.Dr.DMG to TrailBlazer were all intended to cause the Medicare Carriers to approve off-label prescriptions of Trisenox for Medicare reimbursement. The false and misleading statements in those letters had a natural tendency to influence the decision of Medicare Carriers to reimburse Trisenox off-label and were capable of influencing the decision of Medicare Carriers to reimburse Trisenox off-label. In addition, the Medicare carriers relied on CTI's false and misleading communications regarding Trisenox when they listed the drugs and approved indications on their websites, in order to inform physicians of their reimbursement polices. Physicians could and did rely on these posted reimbursement policies to submit claims to the carriers for Medicare reimbursement.

70. Every off-label prescription of Trisenox approved for payment after November 19, 2001 by a Medicare Carrier was a false or fraudulent claim for purposes of the False Claims Act.

*B. Violations of the Medicare-Medicaid Anti-Kickback Act by CTI*

71. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

72. The AKS prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of



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any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by the Medicare program.

73. The AKS not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as any one of its purposes, inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

74. Concern about improper drug marketing practices, like those alleged in this Complaint, prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. Id. Other 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).



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75. The types of remuneration covered by the AKS 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 AKS, 56 Fed. Reg. 35952 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

76. Under the guise of sham "consulting agreements" CTI 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, Defendant routinely paid these physicians significant amounts of money – usually in the range of $500 to $1000 each – for attending a three-hour event. CTI's employees and/or physicians hired by CTI for the purpose of promoting Trisenox off-label presented at these meetings.

77. The "consultant meetings" were not held for the purpose of providing CTI with expert or independent advice. In many cases CTI 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 CTI – other than to attend and absorb the "off-label" marketing pitches.

78. CTI Advisory Boards were held at resort locations offering golf, tennis and spa facilities. Attendees to the Advisory Boards arrived on Friday evening for a cocktail party, attended a 2 ½ to 3 hour breakfast presentation on Saturday morning, and spent the remainder of their time utilizing the resort facilities. Saturday dinner and Sunday breakfast were also provided. All costs for travel, food, drinks, and resort entertainment were paid for by CTI. In addition, attendees received a $1,000 honorarium for their participation. These early meetings had no "feedback" or input from the attendees.



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79. CTI routinely monitored the number of new "off-label" patients who were prescribed Trisenox by their "consulting" physicians. CTI monitored their ROI [return on investment] from these dinners and meetings – that is, prescriptions by physicians for off-label uses of Trisenox. CTI's National Sales Directors prepared monthly reports itemizing their ROI from the dinners and meetings. CTI's Central Region Business Director, Laura Beggrow, noted on October 21, 2001, following an "Advisory Board" meeting in Chicago: "I will continue to track and monitor all ROI [return on investment] following this program and provide this information on my monthly report."

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

81. 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.

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

83. 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.



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84. In or about late 2001, CTI employee 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."

85. Defendant also illegally promoted Trisenox's "off-label" uses by providing financial incentives to physicians for prescribing and speaking on behalf of those non-approved uses.

86. The following physicians are examples of persons who received payment of $1000 plus reimbursement by CTI for their travel and expenses to the Marriot Sawgrass Resort in March and April, 2001, and each submitted claims to Medicare for off-label prescriptions of Trisenox after receiving these improper benefits, remuneration, and compensation: 3.Dr.DEF ($4,620 in claims), 3.Dr.DAF ($370,202 in claims), 3.Dr.TAC ($104,748 in claims); 3.Dr.SB ($42,356 in claims).

87. Defendant 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.

88. 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.

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



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90. CTI's improper compensation of their "consulting physicians" and compensation of doctors who attended lunch or dinner meetings promoting Trisenox constitute violations of the AKS and the FCA.

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

92. CTI's improper compensation of their "consulting physicians" and compensation of doctors who attend lunch or dinner meetings promoting Trisenox constitute violations of the AKS and the FCA.

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

94. 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.

95. On October 22, 2001, Laura Beggrow, CTI's Central Region Business Director, e-mailed her impressions from the Chicago Advisory Board meeting. 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. . . ."



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96. On May 4, 2002, Defendant 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," and "Potential Application for Trisenox in Multiple Myeloma." The presentation binder also contained numerous abstracts (i.e., abridged medical articles) that supposedly support the use of Trisenox "off-label." The strong implication communicated by the materials provided by CTI was that Trisenox was medically accepted for its off-label indications, when CTI knew it was not.

97. When CTI sponsored ostensibly independent Continuing Medical Education ("CME") programs, it manipulated the content of these CME's to improperly suggest that Trisenox was medically accepted and reimburseable for its off-label uses. CTI formulated the content of the presentations, picked the speakers, and selecting the attendees based on their drug usage data, targeting physicians treating MM and MDS – all with the aim of promoting the off-label uses of Trisenox.

98. Even when Defendant retained third-party companies to organize the CME programs to make the CME programs appear "independent," CTI continued to control the content, speakers, and invitees to these events. For instance, in 2002, CTI hired a third party, Envision, Inc., (healthcare education providers) 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 Defendant's "message" was being delivered. CTI's "message" was that Trisenox was medically accepted for its off-label indications. 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



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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.

99. For example, the Jacksonville Advisory Board meeting in Ponte Vedra, Florida, previously noted, belies any notion of impartiality or independence by the presenting physicians. Defendant's 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." By "other therapies" Defendant meant treatments for MM which did not involve the use of Trisenox. In reality, the Advisory Board meetings were off-label marketing meetings organized, controlled, and paid for by Defendant.

100. Among the examples of physicians who were paid to attend so called "Advisory Board" meetings and then subsequently billed Medicare for off-label Trisenox prescriptions: 4.Dr.IR was paid $1000 to attend an "Advisory Board" meeting in Chicago on October 20, 2001, and submitted claims to Medicare for Trisenox totaling $125,952; 4.Dr.RV was paid $1000 to attend an "Advisory Board" meeting in Chicago on April 28, 2001, and billed Medicare for $1200; 4.Dr.JMF was paid $1000 to attend an "Advisory Board" meeting in Chicago on April 28, 2001, and billed Medicare for $5,280; and 4.Dr.PK was paid $1000 to attend an "advisory board" meeting in Berkeley on March 17, 2001, and billed Medicare for $2440. The submission of these claims to Medicare constituted violations of the FCA which were caused by CTI.



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*C. CTI used Clinical Studies to Inflate Commercial Sales of Trisenox in Violation of FDA Rules, then Improperly Required Investigators to Bill Third Party Payers such as Medicare.*

101. FDA regulations prohibit drug manufacturers from charging investigators for investigational drugs used in clinical trials conducted pursuant to an Investigational New Drug exemption ("IND") without the prior waiver in writing by the FDA. See 21 C.F.R § 312.7. Unless a drug qualifies for an exemption as described in Section 312.2, a drug manufacturer sponsoring such a clinical trial must provide the drug to the investigator free of charge. Even if the drug qualifies for an exemption under Section 312.2, a manufacturer sponsoring the study may not "commercialize" an investigational drug by charging a price larger than is necessary to recover the costs of manufacture, research, development and handling of the investigational drug. 21 C.F.R. §312.7(d)(3). Violation of these rules constitutes the illegal promotion of a drug for an unapproved use, thus creating an unapproved new drug. Likewise, if illegally promoted for an unapproved use as described, the drug is misbranded pursuant to 21 U.S.C. §352(f).

102. CTI employees were well aware of the rules governing clinical studies set forth in paragraph 101, and were aware of their duty to comply with them. However, in spite of this knowledge, and without attempting to qualify for an exemption to these rules, CTI embarked on a scheme to use clinical studies to increase the commercial sales of Trisenox. To do this, CTI contracted with physicians to perform what they called "Investigator Sponsor Clinical Trials" ("IST's"), as a means of getting doctors to use the drug off-label. The contracts for these IST's provided that the "study drug"(i.e., Trisenox) was to be supplied by the investigator or the cancer center, who was expected to purchase Trisenox commercially.

103. From 2001 until 2004 CTI paid in excess of $3,077,029 for IST's to market Trisenox but paid only $1,348,745 for conventional clinical studies.



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104. CTI knew that, with some exceptions not applicable here, Medicare – as well as most other private insurance payers – do not provide reimbursement for investigational drugs in the context of clinical studies.

105. CTI was aware that investigators would not be willing to purchase commercial Trisenox without being reimbursed for it. To solve this problem, CTI maintained a "drug replacement program." Under CTI's "drug replacement program, CTI required that Trisenox be billed at full price to third party payers such as Medicare and that such payers deny the claim before CTI would hold the physician harmless by providing free Trisenox to replace the Trisenox which had not been reimbursed by the payers. Patient consent forms approved by CTI also stated that the cost of the study drug would be billed to their insurance carrier or to Medicare. Accordingly, all claims submitted to Medicare in the context of CTI's so called IST program were false claims on the Medicare program which CTI knowingly caused to be submitted to the United States in violation of Section 3729(a)(1) of the FCA.

106. Numerous physicians, including the following physicians, submitted claims to Medicare for reimbursement for Trisenox after receiving funds for ISTs and being required by CTI in the context of ISTs to purchase commercial Trisenox, instead of receiving it free or at CTI cost: James R. Berenson was paid $715,950 to operate clinical studies of Trisenox and billed Medicare for $454,015 for off-label Trisenox prescriptions administered to his patients; and Ralph V. Boccia was paid $222,913 to conduct IST's and billed Medicare for $424,181 for administration of Trisenox off-label. CTI knew that none of these claims for off-label uses of Trisenox were covered by the Medicare program – both because these uses of Trisenox were not medically accepted, and because they were purely experimental. However, CTI, by requiring that physicians conducting IST's purchase commercial drug in violation of the FDA rules, and by conditioning its drug replacement program on the submission by these physicians of false claims to Medicare, caused these physicians to submit false claims to the Medicare program in violation of Section 3729(a)(1) of the FCA.



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107. On December 13, 2001, James Marchese 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).

108. Marchese 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 the 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."

## COUNT I

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

109. The United States realleges and incorporates by reference the allegations contained in paragraphs 1 through 108 of this Complaint.

110. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval in violation of 31 U.S.C. § 3729(a)(1).



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## COUNT II

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

111. The United States realleges and incorporates by reference the allegations contained in paragraphs 1 through 108 of this Complaint.

112. By virtue of the acts described above, CTI knowingly made, used, or caused to be made or used false records and statements, to get the false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)92)

## COUNT III

## Unjust Enrichment

113. The United States realleges and incorporates by reference the allegations contained in paragraphs 1 through 108 of this Complaint.

114. As a result of CTI's conduct described above, the Government was caused to pay thousands of claims for off-label prescriptions of Trisenox submitted by physicians which were not in fact eligible for reimbursement under the Medicare program.

115. CTI benefitted from the Government's reimbursement of the ineligible claims because physicians continued to buy and prescribe Trisenox for off-label uses. Absent off-label prescriptions of Trisenox, the demand for Trisenox, which was approved solely for the treatment of APL, would have been far lower than the actual sales of Trisenox which were inflated by CTI's promotion of off-label prescription.

116. By causing the Government to reimburse off-label sales of Trisenox, CTI was unjustly enriched to the detriment of the United States in an amount to be determined at trial.



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## COUNT IV

## Common Law Fraud

117. The United States realleges and incorporates by reference the allegations contained in paragraphs 1 through 108 of this Complaint.

118. The claims for off-label Trisenox prescriptions that the defendant caused physicians to submit were not covered by the Medicare program because they were for uses of Trisenox which were not medically accepted.

119. CTI caused physicians to submit claims for reimbursement to the Medicare program with knowledge that the Trisenox was not medically accepted for the treatment of its orphan drug indications.

120. The United States, acting in reliance on CTI's misrepresentations, paid the off-label claims submitted by physicians.

121. As a result of the above-described transactions, the United States has been damaged in an amount to be determined at trial.

122. CTI's conduct, as described herein, was willful and malicious, and constitutes conduct for which the law allows the imposition of exemplary damages. Accordingly, the United States requests that exemplary damages be awarded against the Defendants in a sum to be determined at trial.

## COUNT V

## Negligent Misrepresentation

123. The United States realleges and incorporates by reference the allegations contained in paragraphs 1 through 108 of this Complaint.



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124. CTI, through its salespersons and its agents, professed to have special knowledge regarding Medicare reimbursement for Trisenox, and through its salespersons and agents, caused representations to be made that stated or implied that Trisenox was eligible for Medicare reimbursement when prescribed for off-label indications. These representations were false.

125. CTI, was under a duty to use reasonable care to see that any representations it made regarding the question of Medicare reimbursement for Trisenox were correct and truthful, and that the advice, information and opinions it caused to be provided to physicians and Medicare Medical Directors was reliable.

126. It was reasonably foreseeable that physicians and Medicare Medical Directors would rely on the advice, information and opinions CTI caused to be provided to them concerning reimbursement for Trisenox.

127. CTI is therefore liable for the false claims submitted by physicians and paid by Medicare as the direct and proximate damages caused by such misrepresentations.

## PRAYER FOR RELIEF

**WHEREFORE**, the United States prays that, on final trial of this cause, judgment be entered in its favor and against defendants as follows:

1. On the First Cause of Action under the False Claims Act, as amended, for the amount of the United States' damages, multiplied as required by law, and for such civil penalties as are allowed by law;

2. On the Second Cause of Action under the False Claims Act, as amended, for the amount of the United States' damages, multiplied as required by law, and for such civil penalties as are allowed by law;



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3. On the Third Cause of Action, for unjust enrichment for the damages sustained and/or amounts by which the defendants were unjustly enriched or by which defendants retained illegally obtained monies;

4. On the Fourth Cause of Action, for common law fraud, for actual damages in an undetermined amount and for exemplary damages.

5. On the Fifth Cause of Action, for negligent misrepresentation, for actual damages in an undetermined amount and for exemplary damages.

6. For the costs of this action, prejudgment interest, interest on the judgment and for such other and further relief to which plaintiff may be justly entitled.

DATED this 16th day of April, 2007.

Respectfully submitted,

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JEFFREY C. SULLIVAN
UNITED STATES ATTORNEY

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