

ORIGINAL

Judge Pechman

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WESTERN DISTRICT OF WASHINGTON
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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.

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

19
20 3. In conjunction with its off-label marketing scheme, CTI provided doctors and
21 others with money, free travel, food and entertainment, grants, and other valuable goods and
22 services, with the intent to induce physicians to prescribe Trisenox for unapproved
23 indications. This conduct violated the Medicare-Medicaid Anti-Kickback Act ("AKS"), 42
24 U.S.C. § 1320a-7b(b). Because CTI's conduct caused physicians to submit false claims to the
25 Medicare program for non-covered uses of Trisenox, CTI also violated Section 3729(a)(1) of
26 the FCA.

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

16
17 5. As the direct, proximate and foreseeable result of CTI's false and fraudulent
18 conduct, set forth above, CTI (a) caused physicians unwittingly to submit tens of thousands of
19 false claims to the Medicare program seeking reimbursement for Trisenox prescriptions which
20 CTI knew were not medically accepted and therefore ineligible for Medicare reimbursement;
21 and (b) used false or fraudulent statements to get the Medicare program to reimburse millions
22 of dollars of false and fraudulent claims submitted by the physicians. CTI's illegal scheme to
23 promote the prescription of Trisenox for indications which were neither FDA approved nor
24 medically accepted, greatly increased Trisenox sales to the financial benefit of CTI, but
25 caused the Medicare Program to pay millions of dollars for the administration of a drug with
26 no proven medical value to thousands of persons who were dying of cancer.

1 **II. JURISDICTION AND VENUE**

2
3 6. This Court has jurisdiction over the subject matter of this action pursuant to 28
4 U.S.C. §§ 1331, and 1345, and 31 U.S.C. § 3732.

5
6 7. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C.
7 § 3732(a) because Defendant's principal place of business is in the Western District of
8 Washington. Additionally, this Court has personal jurisdiction over Defendant because acts
9 prohibited by 31 U.S.C. § 3729 have occurred in this District. 31 U.S.C. § 3732(a).

10
11 8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because
12 Defendant can be found, resides and transacts business in this, the Western District of
13 Washington and at least one act proscribed by 31 U.S.C. § 3729 occurred in this District.

14
15 **III. PARTIES**

16
17 9. Plaintiff, the United States of America, brings this action on behalf of the
18 Department of Health and Human Services ("HHS"), which is charged with administering the
19 Medicare program through the Centers for Medicare and Medicaid Services ("CMS")
20 formerly known as the Health Care Financing Administration.

21
22 10. Relator, James Marchese, is a resident of New Jersey and a former employee of
23 defendant Cell Therapeutics, Inc. On February 1, 2006, Mr. Marchese filed an action
24 alleging violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, on behalf of himself
25 and the United States Government pursuant to the *qui tam* provisions of the False Claims Act,
26 31 U.S.C. § 3730(b)(1).

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

6
7 **IV. ALLEGATIONS**

8
9 *A. CTI's Off-Label Promotion of Trisenox*

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

23
24 13. A drug is misbranded under the FDCA if, among other things: its labeling is
25 false or misleading in any particular, see 21 U.S.C. § 352(a); the labeling on the drug does
26 not bear adequate directions for use, see 21 U.S.C. § 352(f)(1); and the labeling on the drug
27 does not bear such adequate warnings against use in those pathological conditions, and by
28 children where its use may be dangerous to health, and against unsafe dosage and methods and

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

10
11 14. "Adequate directions for use" is defined by regulation to mean "directions under
12 which the layman can use a drug safely and for the purposes for which it is intended." See 21
13 C.F.R. § 201.5. The "intended use" of a drug refers "to the objective intent of the persons
14 legally responsible for the labeling of drugs." See 21 C.F.R. § 201.128. "The intent is
15 determined by such persons' expressions or may be shown by the circumstances surrounding
16 the distribution of the article[,]" and "may, for example, be shown by labeling claims,
17 advertising matter, or oral or written statements by such persons or their representatives." Id.

18
19 15 On September 25, 2000, the FDA approved an NDA for Trisenox for the
20 treatment of acute promyelocytic leukemia (APL) -- a specific and rare type of leukemia that
21 affects only 10 to 15 percent of the approximately 10,000 patients who are diagnosed with
22 acute myeloid leukemia (AML) in the United States each year. APL is readily identifiable and
23 distinguishable from other forms of AML (and from other cancers) by the presence of a
24 specific chromosomal abnormality, a translocation (i.e., a switch) of genetic material from
25 chromosome number 17 to number 15. APL is clinically associated with a coagulation
26 disorder that results in excessive blood clot formation that eventually exhausts the blood's
27 ability to clot, leading to internal bleeding. Due in part to this bleeding disorder, APL has
28 been recognized as a distinct clinical entity for over 35 years. The FDA approved the NDA

1 for Trisenox *only* for APL in patients who are refractory to, or have relapsed from, retinoid
2 and anthracycline chemotherapy, the standard first-line treatment for APL. Trisenox has
3 never been approved by the FDA for the treatment of any other diseases.
4

5 16. As of the date of the filing of this complaint, Trisenox is the only drug for which
6 CTI has ever obtained marketing approval from the FDA. The sole use for which CTI's NDA
7 for Trisenox was approved by FDA was the treatment of relapsed APL.
8

9 17. The FDA approval of a drug is limited to the specific indications for use listed in
10 the NDA, and the manufacturer may only market the drug for those specific indications.
11 Within the body of the approved NDA (which may consist of volumes of material) is the exact
12 labeling which the manufacturer is required to provide with the drug, and is based on the
13 approved indications for use. The term "labeling" encompasses the actual label attached to the
14 drug's immediate container, as well as all other written, printed, or graphic material,
15 "(1) upon [the drug] or any of its containers or wrappers, or (2) accompanying such [drug]."
16 21 U.S.C. § 321(m). FDA reviews the proposed labeling under 21 U.S.C. § 355(b)(1)(F),
17 because such labeling contains the claims that the drug's manufacturer or sponsor intend to
18 make for its use.
19

20 18. Because a drug approval is limited to those specific uses listed in the NDA, if a
21 manufacturer promotes an approved drug for an indication not in the NDA, it is not covered
22 by the approval, and is therefore an unapproved new drug as to that use. Likewise, if
23 "labeling" for the drug suggests indications for use that are not in the NDA, the drug lacks
24 adequate directions for that use, and the drug is misbranded pursuant to 21 U.S.C. §352(f).
25

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

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

6 |
7 | 20. Medicare is a federal health insurance program for people aged 65 and older as
8 | well as persons under 65 who are blind or disabled. As set forth above, the Medicare
9 | program is administered by CMS, a division of HHS. CMS contracts with private companies
10 | to process and pay claims submitted by Medicare providers for the treatment of Medicare
11 | beneficiaries. Those private companies who process Medicare claims submitted by physicians
12 | are called "Medicare Carriers;" those who process Medicare claims submitted by hospitals are
13 | called "Medicare Intermediaries."

14 |
15 | 21. During the time period covered by this Complaint, Medicare provided limited
16 | benefits for outpatient drugs. Specifically, Medicare paid for anti-cancer drugs in an out-
17 | patient context only if the drug was prescribed for an indication or use for which the drug had
18 | been specifically approved by the FDA, or the drug was prescribed for a "medically accepted
19 | indication" which was defined as a use of the drug that was supported by one or more
20 | citations in certain specified drug compendia published by third parties, see 42 U.S.C.
21 | § 1395x(t)(2)(B)(ii)(I), or by "clinical evidence in peer reviewed medical literature appearing
22 | in publications which have been identified ... by the Secretary." 42 U.S.C.
23 | § 1395x(t)(2)(B)(ii)(II).

24 |
25 | 22. At all times relevant hereto, the Medicare Benefit Policy Manual (the "Manual")
26 | provided additional guidance with regard to Medicare reimbursement for non-FDA-approved
27 | uses of anti-cancer drugs. The Manual provided that Medicare would reimburse for off-label
28 | prescriptions where the off-label use was supported in the text of at least one of three specific

1 drug compendia or one of fifteen specific peer-reviewed medical journals. See Manual at §
2 50.4.5. Of the three compendia identified in the Manual, only two compendia were still in
3 publication during the period relevant to this case: the United States Pharmacopoeia Drug
4 Information (USP-DI) and American Society of Health-System Pharmacists (AHFS).

5
6 23. At all times relevant hereto, the Manual provided with respect to the USP-DI
7 that: "Indications for use appear as accepted, unaccepted, or insufficient data. An indication
8 is considered to be a medically accepted use only if the indication is listed as accepted." See
9 Manual at § 50.4.5(C). Thus to be eligible for reimbursement when prescribed off-label, an
10 anti-cancer drug's use must be "listed as accepted" in the USP-DI.

11
12 24. The Orphan Drug Act (ODA), 21 U.S.C. §§ 360aa-360dd, provides incentives
13 to drug manufacturers to research treatment for diseases and medical conditions that effect a
14 relatively small number of people in the United States, generally under 200,000 individuals.

15
16 25. Under the ODA, the FDA is required to grant orphan drug designation if the
17 sponsor shows a "medically plausible basis for expecting the drug to be effective in the
18 prevention, diagnosis, or treatment of that disease or condition." 21 C.F.R. § 316.25(a)(2).

19
20 26. The fact that a drug has been designated as an orphan drug under the ODA does
21 not mean that the drug is FDA approved for the treatment of that indication; it does not mean
22 that the drug is medically accepted for the treatment of the indication; and the fact that a drug
23 has received orphan designation for a disease has no relevance at all with respect to the
24 question of Medicare reimbursement.

25
26 27. Beginning in 2001, CTI wished to find ways to increase sales of Trisenox by
27 marketing Trisenox for the treatment of diseases other than APL which, due to its rarity,
28 limited the legitimate market for Trisenox. CTI initially hoped to market Trisenox for

1 Multiple Myeloma (MM), a type of cancer which is diagnosed in over 50,000 patients, with
2 15,000 new cases per year; and for Myelodysplastic Syndromes (MDS), a type of cancer
3 which is diagnosed in 36,000 patients, with 15,000 new cases per year. Ultimately, CTI
4 would seek to market Trisenox for chronic myeloid leukemia ("CML"), for chronic
5 lymphocytic leukemia ("CLL"), for various types of liver cancer and for various subtypes of
6 AML (other than APL).

7
8 28. MM, MDS, CML, CLL, liver cancer and AML are all separate and distinct
9 diseases from APL, and treatment appropriate for any one of these diseases is not necessarily
10 appropriate for treatment of the other diseases. The FDA approves drugs for the treatment of
11 each of these diseases separately, and only after appropriate clinical trials demonstrating a
12 drug's efficacy and safety for the treatment of each disease. Trisenox was not approved by the
13 FDA for any indication other than APL.

14
15 29. CTI recognized that it could not successfully sell Trisenox for MM, MDS,
16 CML, CLL, liver cancer or AML unless it convinced oncologists to prescribe Trisenox for
17 these off-label indications. CTI also recognized that it was unlikely that oncologists would
18 prescribe Trisenox for MM, MDS, CML, CLL, liver cancer or AML unless oncologists were
19 convinced that Trisenox was a medically accepted indication for those diseases and thus their
20 prescriptions would be eligible to be reimbursed by the Medicare program. CTI also
21 recognized that it would have to convince the Medical Directors of the Medicare Carriers that
22 Trisenox was a medically accepted indication for MM, MDS, CML, CLL, liver cancer and
23 AML in order for Medicare to reimburse the off-label prescriptions as a matter of routine and
24 thus perpetuate the cycle of prescriptions by oncologists.

25
26 30. Because of the lack of peer-reviewed literature supporting the medical acceptance
27 of the use of Trisenox "off-label," Trisenox has never been listed as medically accepted for
28

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

3
4 31. In September, 2001, CTI employees set in motion a plan to convince oncologists
5 and the Medical Directors of the Medicare Carriers that various off-label uses of Trisenox
6 were eligible for Medicare reimbursement. The plan took advantage of the fact that the USP-
7 DI contained a section dealing with orphan drug designations. This section of the USP-DI
8 contained a list of drugs arranged alphabetically by their generic names and showed any
9 orphan drug designation(s) the drug has obtained from the FDA, the date of the orphan drug
10 designation and, if applicable, the date that the drug received marketing approval for the
11 orphan drug designation. The list of orphan drugs in the USP-DI was separate and apart from
12 and in no way relevant to the question of the medical acceptance of the drug for any particular
13 treatment or indication. High level CTI employees had actual knowledge of the fact that
14 receiving an orphan designation for a drug had nothing to do with the question of medical
15 acceptance of a drug for purposes of treatment, and other CTI employees acted in reckless
16 disregard of this fact.

17
18 32. In order to determine whether a drug is listed as medically accepted for an
19 indication in the compendia and therefore reimbursable, many oncologists, who do not
20 themselves own a copy of the two compendia described in paragraph 22, rely instead on a
21 publication called the Compendia Based Drug Bulletin (the "Bulletin"). The Bulletin is
22 published by the Association of Community Cancer Centers (the "ACCC"). The Bulletin
23 operates as a kind of "Cliff's Notes" for the two Compendia. Copies of the Bulletin are
24 provided free of charge to any oncologist who requests to be included on the ACCC's mailing
25 list, and the Bulletin is also available on-line at the ACCC's web-site (www.accc-cancer.org).

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

5
6 34. In the Fall of 2001, CTI contacted the ACCC about getting the off-label orphan
7 drug indications for Trisenox listed in the Bulletin – *even though there was no peer reviewed*
8 *medical literature indicating that the drug was medically effective for those indications and the*
9 *drug was not listed as medically accepted in either of the two compendia.* In September of
10 2001, James Marchese, a CTI employee, talked to Don Jeweler, the director of
11 communications for the ACCC. Marchese agreed on behalf of CTI to give ACCC an
12 “educational grant” of \$10,000 per year. In exchange, Jeweler agreed on behalf of ACCC to
13 place a banner ad for CTI in a high traffic area on the ACCC website, to list Trisenox’s
14 orphan drug designations in the Bulletin, and to ship 3000 copies of the next three issues of
15 the Bulletin to CTI.

16
17 35. In a letter dated September 20, 2001, Jeweler described the objective of ACCC’s
18 agreement with CTI as follows:

19
20 To raise awareness among oncology health care professionals about
21 Cell Therapeutics, Inc. and Trisenox (including its orphan drug
22 designation for the treatment of MDS, multiple myeloma and
23 APL).

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

26 I heard from Mark and Peter that you may have worked your
27 magic again with a potential way to get us listed for our orphan
28 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

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

3 Agent/Indication(s)	ICD-9 Code(s)
4 * * *	
5 Arsenic Trioxide (Trisenox)†	
6 Acute Promyelocytic Leukemia	205.00, 205.01
6 ★Chronic Myeloid Leukemia★★★	205.10, 205.11
7 ★Multiple Myeloma★★★	203.00 to 203.01
7 ★Myelodysplastic Syndromes★★★	238.7
8 * * *	

9 PUBLICATION KEY

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

13 1 = *USP DI*

14 * * *

15 3 = *AHFS Drug Information*

16 * * *

17 † = FDA approved indication, not yet in compendia.

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

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

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

8
9 Q. What is Compendia and why is it important?

10 A. Compendia literally refers to any text book used by medical
11 professionals to determine treatment options for a given
12 disease. The USP-DI and AHFS are the only government
13 recognized books that establish acceptable treatment
14 patterns. The legislature uses "Compendia listed" to
15 describe these books and therefore these 2 book sets
16 determine what is a reimburseable practices [sic] in medicine.

17 Q. What is the ACCC and how does it get involved with
18 Compendia?

19 A. The ACCC is one of the most respected and largest cancer
20 focused organization in the country. It facilitates community
21 cancer center practices. The ACCC reviews the USP-DI
22 and AHFS and puts out a footnotes [sic] called the
23 Compendia Bulletin. This bulletin is relied upon by carriers
24 and community practices to determine reimburseable
25 treatments. (The actual USP-DI and AHFS are volumes of
26 medical text containing 1000's of pages that would be
27 impossible for office managers and carriers to follow, so the
28 ACCC put together cliff notes.)

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

1 physicians and their medical staff into believing that off-label uses of Triscnox were medically
2 accepted and reimbursable by Medicare.

3
4 41. On November 27, 2001, upon receipt of the 3000 copies of the November 2001
5 issue of the Bulletin, Peter Sportelli, the head of CTI's sales force, wrote the following email
6 message to Marchese:

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

17 42. As part of its \$10,000 deal with the ACCC, CTI received 3000 copies of the
18 February 2002, Vol. 11 No. 1, issue of the Bulletin. The listing for Trisenox in this issue of
19 the Bulletin was identical to the November 2001, Vol. 10 No. 4, issue described in paragraph
20 37, above, and was false and misleading for the same reasons set forth in paragraph 38,
21 above. On information and belief, all or nearly all of the 3000 false and misleading February
22 2002, Vol. 11 No. 1, issues were distributed to physicians by CTI salespeople.

23 43. At the times it distributed the February 2002, Vol. 11 No. 1, issues of the
24 Bulletin to physicians, CTI knew that the FDA had not approved Trisenox for CML, MM and
25 MDS but did not inform the physicians to whom it distributed the Bulletin of this fact. CTI
26 also knew that CML, MM and MDS were not recognized in the compendia as medically
27 accepted indications for Trisenox, but CTI did not inform physicians of this fact. CTI also
28 knew that Trisenox was neither medically accepted nor reimbursable 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 reimbursable.

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

3 Agent/Indication(s)	ICD-9 Code(s)
4 ***	
5 Arsenic Trioxide (Trisenox)	
6 ★Acute Myelocytic Leukemia★★★	
6 Acute Promyelocytic Leukemia	205.00, 205.01
7 Chronic Myeloid Leukemia★★★	205.10, 205.11
7 Multiple Myeloma★★★	203.00 to 203.01
8 Myelodysplastic Syndromes★★★	238.7

8 ***

9 PUBLICATION KEY

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

12 1 = USP DI

13 ***

14 3 = AHFS Drug Information

15 ***

16 † = FDA approved indication, not yet in compendia.

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

18
19 45. The May 2002, Vol. 11 No. 2, issue of the Bulletin was false and misleading
20 because it stated that each listed indication for Trisenox was "recognized in both compendia,"
21 implying that such uses were medically accepted. In fact, Trisenox was not "recognized" in
22 either of the compendia for AML, CML, MM or MDS but was merely listed in the USP-DI
23 as having been designated as an orphan drug for MM.

24
25 46. On information and belief, all or virtually all copies of the 3000 false and
26 misleading May 2002, Vol. 11 No. 2, issues of the Bulletin that CTI received were distributed
27 to physicians by CTI salespeople.
28

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

8
9 48. As part of its \$10,000 deal with the ACCC, CTI received 3000 copies of the
10 August 2002, Vol. 11 No. 3, issue of the Bulletin. The listing for Trisenox in this issue of
11 the Bulletin was identical to the May 2002, Vol. 11 No. 2, issue described in paragraph 44,
12 above, and was false and misleading for the same reasons set forth in paragraph 45 above. On
13 information and belief, all or nearly all of the 3000 false and misleading August 2002, Vol. 11
14 No. 3, issues were distributed to physicians by CTI salespeople.

15
16 49. At the times it distributed copies of the August 2002, Vol. 11 No. 3, issue of the
17 Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations
18 that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No.
19 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML,
20 MM and MDS. CTI also knew that AML, CML, MM and MDS were not recognized in the
21 compendia as medically accepted indications for Trisenox, but CTI did not inform physicians
22 of this fact.

23
24 50. On information and belief, CTI made the following additional purchases of
25 copies of the ACCC Bulletin: 3000 copies of the May 2003, Vol. 12 No. 2, issue. The listing
26 for Trisenox in this issue of the Bulletin was identical to the May 2002, Vol. 11 No. 2, issue
27 described in paragraph 44, above, and was false and misleading for the same reasons set forth
28 in paragraph 45, above. On information and belief, all or nearly all of the 3000 false and

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

3
4 51. At the times it distributed copies of the May 2003, Vol. 12 No. 2 issue of the
5 Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations
6 that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No.
7 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML,
8 MM and MDS. CTI also knew that AML, CML, MM and MDS were not recognized in the
9 compendia as medically accepted indications for Trisenox, but CTI did not inform physicians
10 of this fact.

11
12 52. On information and belief, CTI purchased 2400 copies of the August 2003, Vol.
13 12 No. 3, issue of the Bulletin. The entry for Trisenox in this issue stated:

14 Agent/Indication(s)	ICD-9 Code(s)
15 ***	
16 Arsenic Trioxide (Trisenox)	
17 Acute Myelocytic Leukemia★★★	205.0
18 Acute Promyelocytic Leukemia	205.0 ⁻
19 ★Chronic Lymphocytic Leukemia	204.1 ⁻
20 Chronic Myeloid Leukemia★★★	205.1 ⁻
21 ★ Liver★★★	155.
22 Multiple Myeloma★★★	203.0 ⁻
23 Myelodysplastic Syndromes★★★	238.7 ⁻

24 ***

25 PUBLICATION KEY

26 Unless otherwise noted, drugs/indications are recognized in
27 both compendia. Drugs marked as ★★★ have orphan drug
28 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.

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

6
7 54. On information and belief, all or nearly all of the 2400 false and misleading
8 August 2003, Vol. 12 No. 3, issues were distributed to physicians by CTI salespeople.

9
10 55. At the times it distributed copies of the August 2003, Vol. 12 No. 3, issue of the
11 Bulletin to physicians, CTI failed to take any affirmative step to correct the misrepresentations
12 that CTI had spread in the November 2001, Vol. 10 No. 4, and February 2002, Vol. 11 No.
13 1, issues of the Bulletin regarding the claim that the FDA had approved Trisenox for CML,
14 MM and MDS. CTI also knew that AML, CML, CLL, Liver, MM and MDS were not
15 recognized in the compendia as medically accepted indications for Trisenox, but CTI did not
16 inform physicians of this fact.

17
18 56. On information and belief, CTI also purchased 5000 copies of the November
19 2003, Vol. 12 No. 4 issue; 500 copies of the May 2004, Vol. 13 No. 2, issue; 1000 copies of
20 the August 2004, Vol. 13 No. 3, issue; 1000 copies of the February 2005, Vol. 14 No. 1,
21 issue. The listing for Trisenox in these issues of the Bulletin were identical to the August
22 2003, Vol. 12 No. 3, issue described in paragraph 52, above, and was false and misleading
23 for the same reasons set forth in paragraph 53 above. On information and belief, all or nearly
24 all of these 7500 false and misleading copies of these Bulletins were distributed to physicians
25 by CTI salespeople.

26
27 57. At the times it distributed the copies of the November 2003, Vol. 12 No. 4
28 issue, May 2004, Vol. 13 No. 2, issue; August 2004, Vol. 13 No. 3, issue; and February

1 2005, Vol. 14 No. 1, issue of the Bulletin to physicians, CTI failed to take any affirmative
2 step to correct the misrepresentations that CTI had spread in the November 2001, Vol. 10 No.
3 4, and February 2002, Vol. 11 No. 1, issues of the Bulletin regarding the claim that the FDA
4 had approved Trisenox for CML, MM and MDS. CTI also knew that AML, CML, CLL,
5 Liver, MM and MDS were not recognized in the compendia as medically accepted indications
6 for Trisenox, but CTI did not inform physicians of this fact.

7
8 58. In addition to providing copies of the false and misleading Bulletin to doctors, as
9 described above, CTI salespeople routinely told the physicians with whom they met that
10 because Trisenox's off-label uses were listed in the Bulletin, Trisenox had obtained
11 Compendia listing. CTI intended that these statements would cause doctors to believe that the
12 drug was medically accepted for the indications in question and hence was eligible for
13 reimbursement thus leading doctors to prescribe Trisenox off-label and submit those off-label
14 prescriptions to Medicare for reimbursement.

15
16 59. Physicians and other medical professionals relied on the false and misleading
17 copies of the Bulletin which were provided to them by CTI salespeople and further relied on
18 the false and misleading statements made by CTI salespeople to the effect that Trisenox had
19 obtained Compendia listing. Because of CTI's misrepresentations, physicians and other
20 medical professionals were misled into believing falsely that Trisenox was medically accepted
21 for its off-label indications and prescribed Trisenox for their patients with these indications.
22 These physicians also believed that Trisenox's off-label orphan-designated indications were
23 eligible for Medicare reimbursement and submitted claims for payment to Medicare Carriers
24 for Trisenox that was prescribed for off-label indications. On information and belief, among
25 the physicians who were misled by CTI's scheme to defraud were the following:¹ 1.Dr.JS,
26 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,

27
28 ¹ A complete and separate *Listing of Physicians Referencing this Complaint In Intervention*
is being filed concurrently and Under Seal.

