BLANK ROME LLP
The Chrysler Building
405 Lexington Avenue
New York, NY 10174
(212) 885-5000
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF UNDER SEAL	)	_____CIV_____
v.	)	**FILED UNDER SEAL**
DEFENDANTS UNDER SEAL	)	**COMPLAINT AND JURY DEMAND**

BLANK ROME LLP
The Chrysler Building
405 Lexington Avenue
New York, NY 10174
(212) 885-5000
Attorneys for Plaintiff

UN ITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* JOHN DOE, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, *Plaintiffs*, v. CEPHALON, INC. and JOHN DOES # 1-100, FICTITIOUS NAMES, *Defendants*.	)	_____CIV_____ **FILED UNDER SEAL**

TABLE OF CONTENTS

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by John Doe, by and through his attorneys, against Defendants pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *et seq.*; the Colorado Medicaid False Claims Act, COLO. REV. STAT. § 25.5-4-304 (2010) *et seq.*; the Connecticut False Claims Act, 2009 CONN. PUB. ACTS NO. 09-5 (Sept. Spec. Sess.), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.;* the Florida False Claims Act, FLA. STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN.§ 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act. HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE § 5-11-5.5, (2007) *et seq.*, the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.;* the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A), (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Minnesota False Claims Act, MINN. STAT. § 15C.01 *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 (2005), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 265 (2007); the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1 (2007), *et*

seq.; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605, *et. seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*, and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.*, ("State *qui tam* statutes" or "*Qui Tam* States").

I. STATEMENT OF THE CASE

1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators under the False Claims Act and the State *Qui Tam* statutes.

2. Cephalon is a pharmaceutical company that has implemented a scheme to submit and cause to be submitted hundreds of thousands of false claims to federal and state healthcare programs by systematically and illegally promoting Treanda® (a highly potent oncology drug that was developed in East Germany in the 1960s) and Fentora® (a highly potent opioid analgesic) for unapproved, off-label uses throughout the United States.

3. The essence of Cephalon's scheme to illegally promote Treanda® is an effort to promote the drug in combination with rituximab for the front-line treatment of indolent (slowly-progressing) non-Hodgkin's lymphoma, even though the FDA has not approved such use. As described in detail below, the focus of Cephalon's illegal marketing campaign has been a deeply flawed study by Dr. Mathias Rummel, a German scientist, which provides only unreliable

evidence of Treanda®'s efficacy. Cephalon's scheme to illegally drive sales growth is particularly troubling because of the drug's very serious, and potentially fatal, side effects, and the fact that it is substantially more expensive than the standard-of-care, thus increasing costs for both Government Programs and patients. Treanda® is considerably more expensive than the generic drugs it is being marketed to replace to treat iNHL front line (as defined below).

4. The essence of Cephalon's scheme to illegally promote Fentora® is an effort to promote the drug to pain specialists for the treatment of non-cancer pain, even though it only is approved for the treatment of "breakthrough cancer pain." As described in detail below, although Fentora® is approved only for the treatment of breakthrough pain in cancer patients, Cephalon uses only its general pain sales force—not its oncology sales force—to promote Fentora® to thousands of doctors who do not treat cancer patients at all. Cephalon does this in a cynical effort to expand sales beyond the narrow patient population for which Fentora® is approved. Its conduct is particularly troubling because Fentora® is a very dangerous drug with potentially fatal side effects. Fentora® also happens to be substantially more expensive than other opioid therapies.

5. Cephalon's goal in developing (and deploying) its illegal schemes was to increase sales of Treanda® and Fentora® by promoting them beyond their limited FDA approvals. At the same time, Cephalon knew that its illegal promotional activities would cause these drugs to be prescribed off-label to beneficiaries of state and federal government programs, such as Medicare and Medicaid, that provide reimbursement for certain healthcare expenses (the "Government Programs"). Cephalon deployed its illegal schemes knowing and intending that patients or their physicians would submit claims for reimbursement of their off-label use of Treanda® and Fentora® by Government Programs, and they did so. These false claims cheated the Federal

Government and *Qui Tam* States out of hundreds of millions of dollars that should not have been paid, thereby improperly enriching Defendants.

6. Cephalon's illegal conduct in promoting Treanda® and Fentora® as it did is particularly surprising in light of the company's agreement in September 2008 to pay $425 million to settle civil and criminal charges that it illegally promoted the off-label use of Actiq®, Provigil® and Gabitril®, which were the only drugs it was marketing at that time. Cephalon's subsequent illegal promotion of Treanda® and Fentora® thus flies in the face of the Corporate Integrity Agreement that Cephalon signed as part of the September 2008 settlement, wherein the company pledged, among other things, to cease all further off-label marketing.

II. JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Defendants because, among other things, Defendants transact business in this District, and engaged in wrongdoing in this District.

9. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

10. The causes of action alleged herein are timely brought because, among other things, of efforts by Defendants to conceal from the United States its wrongdoing in connection with the allegations made herein.

III. PARTIES

A. PLAINTIFF/RELATOR JOHN DOE

11. Plaintiff/Relator John Doe ("Relator Doe") is a resident of Pennsylvania. Relator Doe has filed this Complaint with the John Doe pseudonym to delay, and perhaps prevent, the very real possibility of employment retaliation. John Doe is currently employed by Defendant Cephalon as a senior level manager. His responsibilities have provided high-level access to Cephalon's decision-making process in nearly all of its pharmaceutical sales operations, including marketing, sales, education, reimbursement, and compliance.

12. Relator Doe is an original source of the allegations in this Complaint, and these allegations are not based upon publicly-disclosed information. He has provided the Government with material information prior to the filing of this Complaint in accordance with 31 U.S.C. § 3730(b)(2). Also prior to filing this Complaint, Relator Doe brought the wrongdoing described herein to the attention of Cephalon.

B. DEFENDANT CEPHALON, INC.

13. Cephalon, Inc. ("Cephalon"), is a Delaware corporation founded in 1987, with its principal place of business located at 41 Moores Road, Frazer, Pennsylvania. Cephalon employs approximately 4,000 people throughout the United States and Europe.

14. As described more fully herein, Cephalon is engaged in the promotion, distribution, commercialization, and sale of products for central nervous system, inflammatory disease, pain, and oncology therapeutic areas. Throughout the relevant period, Cephalon marketed and sold substantial quantities of its pharmaceutical products, including Treanda® and Fentora®, throughout the State of New York and in the United States.

15. The founder and Chief Executive Officer of Cephalon is Frank Baldino, who is credited with developing the company's business strategy. He also is credited with developing Cephalon's illegal drug promotion strategies, which he has encouraged, and from which he has personally profited. *See* "He's Just Being Frank," http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=408472 (March 1, 2007). In 2009, Baldino's compensation was $11.1 million, including a base salary of $1.3 million, $4.5 million in stock awards, $4 million in option awards and $1.3 million in non-equity incentive plan compensation. (He received 160,000 stock options and 80,000 RSUs.) On August 25, 2010, Cephalon announced Baldino had taken a medical leave of absence, effective immediately.

16. Cephalon has a history of non-compliance with Federal laws designed to prohibit the off-label promotion of pharmaceuticals. As indicated, the company settled criminal and civil charges in 2008 relating to its off-label promotion of Actiq®, Provigil®, and Gabitril®, which were the only drugs then in its portfolio. As part of that settlement, Cephalon entered into a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of the Inspector General ("OIG"), that required, among other things, that Cephalon: (i) establish a program to monitor and evaluate sales representatives' interactions with healthcare providers, (ii) identify potential off-label promotional activities; and (iii) self-report instances of off-label promotion. The settlement notwithstanding, Acting United States Attorney Laurie Magid, was highly critical of Cephalon, stating:

> This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.

The head of the Philadelphia Regional Office of the OIG, Patrick Doyle, added that the Cephalon case "should serve as still another warning to all those who break the law in order to improve their profits. OIG, working with our law enforcement partners, will pursue and bring to justice those who would steal from vulnerable beneficiaries and the taxpayers."

17. Unfortunately, Cephalon's off-label promotion has continued unabated. Cephalon has illegally marketed and sold Treanda® and Fentora® off-label with the intention that such off-label sales would be paid or reimbursed by a variety of Government Programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association ("BCBSA"), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program (including Medicare Part B, Medicare Part C/Medicare+Choice, Medicare Part D, and Medicare Advantage), the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE") and the Veteran's Health Administration ("VHA") (collectively, the "Government Programs").

C. DEFENDANTS JOHN DOES #1-100

18. John Does #1-100, fictitious names, are individuals, corporations, limited liability companies, or other lawful business entities through which Defendants do business in the United States and internationally, and who are unknown co-conspirators who conspired with Cephalon to perpetuate the schemes described herein. To the extent that any of the conduct or activities described in this Complaint were not performed by Defendants, but by the individuals or entities described herein as John Does #1-100, fictitious names, any reference herein to Defendants

under such circumstances, and only under such circumstances, refers also to John Does #1-100 and/or other co-conspirators who conspired with Defendants to perpetrate the schemes described herein. As a result of actions of John Does #1-100, the *Qui Tam* States and Federal Government Programs have suffered financial harm.

IV. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

A. THE FRAUDULENT MARKETING SCHEME FOR TREANDA®

19. It was the plan and purpose of Cephalon's Fraudulent Marketing Scheme for Treanda® to grow the patient population for Treanda® dramatically because it knew that Treanda® faced Orphan Drug expiration in 2015. The most lucrative potential market for Treanda® was for the front-line treatment of indolent non-Hodgkin's lymphoma ("iNHL"). ("Front-line" treatment is usually the standard treatment—the "gold standard" given when someone is diagnosed with a particular disease or condition). But, any potential FDA approval for front-line iNHL use would be years away. Thus, Cephalon began a reckless and illegal scheme to promote Treanda® as an effective front-line therapy, in combination with Rituxan® (rituximab), for the treatment of iNHL, even though Treanda® is not FDA-approved for such use. Cephalon implemented this scheme by:

(i) educating its sales force on data from Dr. Rummel's study (the "Rummel Study"), which provided only limited (and unreliable), anecdotal support for the use of Treanda® as front-line therapy for the treatment of iNHL;

(ii) using the Rummel Study to promote Treanda® to oncologists off-label, in combination with rituximab, as front-line therapy for the treatment of iNHL;

(iii) using bogus "market research surveys" and Advisory Board meetings to disseminate the off-label Rummel Study message to prescribing physicians;

(iv) converting iNHL front line continuing medical education programs into promotional programs to promote the Rummel Study to prescribing physicians; and

(v) using "In-Practice Programs," which featured speakers on off-label use of Treanda®, to drive off-label sales through large oncology group purchasing organizations, such as ION, US Oncology, and Onmark.

20. Cephalon did these things knowing (and intending) that they would cause physicians to prescribe Treanda® off-label as front-line therapy for the treatment of iNHL, and knowing (and intending) that the same physicians then would submit false and fraudulent claims for reimbursement to Government Programs, which they did.

21. Cephalon's illegal, off-label promotion of Treanda® involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of causing the Federal Government and *Qui Tam* States to pay for false or fraudulent claims. Defendants' conduct had a material effect on the Governments' decision to pay for Treanda®. Had the Federal and *Qui Tam* State Governments known that the claims were the result of illegal, off-label promotion, they would not have been paid.

22. Cephalon has profited handsomely from this illegal, off-label marketing scheme, which is ongoing.

B. THE FRAUDULENT MARKETING SCHEME FOR FENTORA®

23. It was the plan and purpose of Cephalon's Fraudulent Marketing Scheme for Fentora® to convert the off-label use of its pain drug Actiq®, which had been used nearly 100% off-label and had lost patent protection in 2008, over to its newly-approved drug Fentora®. Immediately after Actiq® lost its patent protection (and generics began to come on the market), Cephalon launched Fentora® and began an "aggressive" (and illegal) campaign to convert the Actiq® off-label patient population by promoting Fentora® to the same pain specialists (not oncologists) to whom it had previously been promoting Actiq®. Cephalon did so even though Fentora® had been FDA approved *only* for the treatment of "breakthrough cancer pain." Cephalon assigned sole promotional responsibility for Fentora® to its pain sales force, and not its oncology sales force, despite knowing that approximately 90 percent of oncologists treat their patients diagnosed with breakthrough cancer pain themselves, and thus do not refer them to pain specialists. Hence, the doctors Cephalon is promoting to *do not use Fentora® on-label.*

24. Cephalon did these things knowing (and intending) that they would cause physicians to prescribe Fentora® off-label for conditions other than breakthrough cancer pain, and knowing (and intending) that the same physicians then would submit false and fraudulent claims for reimbursement to Government Programs, which they did.

25. Cephalon's illegal, off-label promotion of Fentora® involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of causing the Federal Government and *Qui Tam* States to pay for false or fraudulent claims. Defendants' conduct had a material effect on the Governments' decision to pay for Fentora®. Had the Federal and *Qui Tam* State Governments known that the claims were the result of illegal, off-label promotion, they would not have been paid.

26. Cephalon has profited handsomely from this illegal, off-label marketing scheme, which is ongoing.

V. BACKGROUND OF THE REGULATORY FRAMEWORK

A. THE FOOD AND DRUG ADMINISTRATION REGULATORY SYSTEM

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed

27. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

28. Under the FDCA, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements About a Drug's Use

29. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels—including all marketing

and promotional materials relating to the drug—may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

30. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

31. A manufacturer, like Cephalon, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

32. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or

frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved to treat adults.

33. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

34. The FDA has stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. 21 C.F.R. § 99.101 *et seq*. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See id.* § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." *Id.* § 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. *Id.* § 99.101(b)(2).

35. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

36. And, off-label information may be disseminated only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination, and the materials themselves are submitted in unabridged form and are neither false nor misleading. 21 U.S.C. §§ 360aaa(b), (c); 360aaa-1.

37. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body—the FDA. And the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

B. THE ROLE OF THE COMPENDIA

38. Congress has adopted a Compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." *See* Social Security Act §§ 1927(g)(1)(B)(i) and (k)(6). The statute permits reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."

39. Pursuant to its statutory authority, the Centers for Medicare and Medicaid Services ("CMS") further defines the circumstances under which a prescription for off-label use of an oncology drug can be reimbursed under Medicaid, Medicare or the other Government Programs. Since June 1, 2008, CMS has recognized four so-called "Compendia" to be used in determining whether drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen are to be considered as being medically accepted. *See, e.g.*, Medicare Benefit Policy Manual (the "Policy Manual"), Ch. 15, Sec. 50.4.4. Those Compendia are the American Hospital Formulary Service Drug Information ("AHFS") (effective for reimbursement purposes as of June 5, 2008), the National Comprehensive Cancer Network ("NCCN") (effective for reimbursement purposes as of June 5, 2008), Thomson Micromedex DrugDex ("DrugDex") (effective for reimbursement purposes as of June 10, 2008), and Clinical Pharmacology (effective for reimbursement purposes as of July 2, 2008).

40. Prior to June 1, 2008, CMS recognized only AHFS, and two now defunct Compendia called American Medical Association Drug Evaluations ("AMA-DE") and United States Pharmacopeia-Drug Information ("USP-DI").

41. It merits emphasis that even where an off-label use is reimbursable under the Compendia, drug companies may not legally promote that use to healthcare professionals or patients.

42. The Compendia play a significant role in determining whether and how particular oncology drugs will be prescribed to treat different forms of cancer, as well as the extent to which such uses will be reimbursed by Government Programs. Thus, their publishers wield extraordinary influence on both the course, and the cost, of cancer care. As described more fully

below, drug companies like Cephalon have corrupted that influence to their own economic advantage.

C. PRESCRIPTION DRUG PAYMENT UNDER GOVERNMENT PROGRAMS

43. Whether an FDA-approved drug is approved for a particular indication (*i.e.*, use) determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program

44. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

45. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

46. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug Compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6). During the time period relevant to this Complaint, Cephalon promoted off-label uses of Treanda® and Fentora® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug Compendia specified by the Medicaid statute.

2. The Medicare Program

47. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

48. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

49. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

50. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

51. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.

52. During the time period relevant to this Complaint, Cephalon promoted off-label uses of Treanda® and Fentora® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling, nor supported by the specified Compendia.

3. Reimbursement Under Other Government Programs

53. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs. For example:

(i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.

(ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100 percent service-connected disabilities.

(iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

54. During the time period relevant to this Complaint, Cephalon promoted off-label uses of Treanda® and Fentora® that were not eligible for reimbursement under any of the various Federal health care programs.

4. Reimbursement of Treanda® and Fentora® Under Government Programs

55. Treanda® is an injectable cancer drug that is covered by Medicare Part B, which provides coverage for drugs billed by physicians and provided "incident to physician service" for that patient. Physicians who administer Treanda® intravenously in their offices or clinics must first purchase the drug directly from Cephalon or from a wholesaler; the physician or clinic then seeks reimbursement from Medicare by billing under a J-Code from the CMS Healthcare Common Procedure Coding System. The J-Code for Treanda® is J9033.

56. Fentora® is produced in a tablet form, is taken orally by the patient, and is dispensed at pharmacies for patients with a prescription. Pharmacies seek reimbursement from

Medicare based on a drug's National Drug Code ("NDC") number. The NDC codes for Fentora® are:

Fentora® NDC Codes

Package Strength	Code
100 mcg	63459-541-28
200 mcg	63459-542-28
300 mcg	63459-543-28
400 mcg	63459-544-28
600 mcg	63459-546-28
800 mcg	63459-548-28

57. Treanda® is also reimbursable under Medicare Part D. The NDC codes for Treanda® are:

Treanda® NDC Codes

Package Strength	Code
25 mg in 8 mL Vial	63459-390-08
100 mg in 20 mL Vial	63459-391-20

58. Treanda® and Fentora® also are reimbursable by Medicaid when the patient is not eligible for Medicare, but meets certain qualification criteria. While the Department of Health and Human Services oversees the Medicaid operation and the Centers for Medicare and Medicaid Services sets the program's parameters, individual states have their own agencies that are responsible for their Medicaid programs. These state Medicaid agencies also provide reimbursement for Treanda® and Fentora®. Cephalon has derived substantial profits from Medicaid reimbursements for Treanda® and Fentora®.

VI. TREANDA®: FRAUDULENT MARKETING SCHEME TO PROMOTE OFF-LABEL USE

59. On May 12, 2005, Cephalon announced it had acquired Salmedix, Inc., a privately-held oncology drug development company based in San Diego, California, for $160 million. Along with that purchase came the rights to sell SDX-105 (Treanda®) in the United States and Canada. At the time SDX-105 was still under investigation in Phase II clinical trials and showed promise to treat chronic lymphocytic leukemia ("CLL") and indolent (slowly progressing) non-Hodgkin's lymphoma ("iNHL").

60. On September 21, 2007, Cephalon announced that it had submitted a New Drug Application ("NDA") to the FDA, requesting approval of Treanda® (bendamustine HCl) for the treatment of patients with CLL. Then, on December 31, 2007, Cephalon submitted an NDA requesting approval of Treanda® for the treatment of patients with iNHL who have progressed during or following treatment with rituximab or a rituximab-containing regimen.

A. BACKGROUND ON TREANDA® ONCOLOGY MARKET

1. Drug Company Development of Oncology Drugs

61. Despite predictions for nearly four decades that a cure for cancer is near, cancer death rates have changed little, and most new cancer drugs are inordinately expensive while giving patients few, if any, added weeks of life. *See* Gardiner Harris, *Forty Years' War Where Cancer Progress Is Rare, One Man Says No*, N.Y. TIMES, Sept. 15, 2009, at A1, *available at*, http://www.nytimes.com/2009/09/16/health/policy/16cancer.html (last visited Aug. 17, 2010).

62. When President Nixon launched the war on cancer in 1971, he separated the budget for the National Cancer Institute ("NCI") from the rest of the budget for the National Institutes of Health ("NIH") in order to focus more attention and resources on cancer research.

The budget of the NCI in 2005 was $4.87 billion. In addition, there are 260 registered nonprofit organizations devoted to cancer—more than the total number devoted to heart disease, stroke, AIDS, and Alzheimer's Disease combined. These nonprofits reported more than $2.2 billion in gross receipts in 2005.

63. Direct medical costs including inpatient and outpatient care, drugs, and devices accounted for $74 billion, while $17.5 billion was attributed to indirect morbidity costs (*e.g.*, lost productivity) and $118.4 billion was attributed to indirect mortality costs (*e.g.*, lost productivity due to premature death). *Id.*

64. Because cancer generally afflicts older persons, cancer expenditures will be of even greater concern in the future, as the so-called "baby boomer" population swells the ranks of the Medicare program from 42.5 million in 2005 to almost 70 million by 2030. *See* U.S. Census Bureau: U.S. Interim Projections By Age, Sex, Race, and Hispanic Origin, Mar. 2004 update, *available at*, http://www.census.gov/population/www/projections/usinterimproj/ (last visited Aug. 17, 2010). That cancer recently surpassed heart disease as the leading killer of Americans under age 85 tends to confirm this trend, as well as the extent of unmet clinical need in oncology relative to other diseases.

65. In 2004, Medicare payments for all Part B drugs for medical oncology totaled $5.3 billion ($2.3 billion for chemotherapy, and $1.5 billion for erythroid growth factors), and drugs prescribed by oncologists accounted for more than forty percent of all Medicare drug spending. *See* Meropol, *et al.*, 25 J. CLIN. ONC. at 181.

66. Pharmaceutical companies have sought to capitalize on the increasing demand for cancer treatments "at any cost" by introducing an increasing number of marginally beneficial

drugs at very high prices, and by expanding the patient populations for those drugs through off-label marketing activities.

67. Indeed, the "at any cost" approach to cancer treatment has led companies like Cephalon to promote their oncology treatments aggressively, but with only marginal scientific support, knowing that physicians treating a desperate patient base will experiment with their drugs without regard to cost and, in many cases, without regard to a product's FDA-approved label.

68. Feeding this cycle, most U.S. oncologists derive income directly from the drugs they prescribe due to the manner in which they are administered (in clinical settings) and reimbursed. This creates a disturbing incentive to use more costly treatments, even though they may offer only marginal added value (if any) to patients. Recent data suggest that reimbursement does influence oncologists' prescribing choices, at least for Medicare beneficiaries. *See* Jacobson, et al., "Does reimbursement influence chemotherapy treatment for cancer patients?" Health Affairs 25:437-443 (2006). Thus, although reimbursement may have little effect on the oncologist's primary decision *whether* to administer palliative chemotherapy to patients with advanced solid tumors, it does appear to affect the choice of *how* to treat (*i.e.*, which drugs to use). *Id.* at 442. Once a decision to administer chemotherapy is made, physicians receiving more generous oncology drug reimbursements tend to use more costly treatment regimens. *Id.* This has fed Cephalon's (and other companies') willingness to push unproven medications off-label, in lieu of less expensive, on-label treatments.

2. The Unchecked Influence of the Drug Companies on the Compendia to Approve Off-Label Uses of Oncology Drugs

69. Particularly with oncology drugs, the Compendia publishers wield extraordinary influence with respect to which drugs will be used and how they are reimbursed. *See* discussion *supra*. And, they exercise that influence to "approve" new cancer treatments even when there is little clinical evidence behind a particular citation.

70. Drug companies like Defendant Cephalon recognize the important role that the Compendia play in determining whether and how particular drugs will be used, and they have used their financial might to corrupt the Compendia process. Thus, several of the key oncology Compendia have close financial ties to the drug industry. *See* Reed Abelson & Andrew Pollack, *Medicare Widens Drugs It Accepts for Cancer*, N.Y. TIMES, Jan. 26, 2009, at A1, *available at*, http://www.nytimes.com/2009/01/27/health/_27cancer.html (last visited Aug. 17, 2010).

71. The most influential of these Compendia is developed by the National Comprehensive Cancer Network ("NCCN"). "Consensus groups" like NCCN require industry funding to develop their Compendia and practice guidelines ("Guidelines"). Thus, they propose topics that will attract industry funding (*e.g.*, a guideline on *how* to use a product, but not *whether* it should be used). Among the topics proposed to potential funders, drug companies favor topics and questions for which the evidence is most likely to support conclusions favorable to their particular drug products. The lack of transparency "limits the ability of guideline readers to consider financial relationships and conflicts of interest as part of their assessment of the credibility of a set of guidelines." *See* The National Academies: Institute of Medicine: Conflict

of Interest in Medical Research, Education, and Practice, at 205 (April 21, 2009) (Full Text Available at www.nap.edu).

72. Over the past decade, the NCCN Guidelines and the associated NCCN Compendium have become the "standard" in determining the standard of care in oncology in the United States. However, there has been little transparency in how the NCCN panels determine what drug regimens to recommend. Not only is there a lack of disclosure of what (and how) drug companies submit information for inclusion in the NCCN Guidelines and Compendium, there has been no disclosure of the panel deliberations. There are no published requirements for the minimum level of evidence required for NCCN approval, no disclosure of what "evidence" the NCCN panels have relied on for their determinations, no public information regarding the actual deliberations over the submissions, nor any information about which expert panelists participated, which recused themselves, nor what the final votes were for each approval.

73. Most troubling is that the NCCN, its Guidelines, its Compendium and its panelists remain laced with numerous conflicts of interest due to their substantial financial ties to the drug industry in general, and to Cephalon in particular.

74. The website for the NCCN non-Hodgkin's lymphoma ("NHL") panel discloses that a number of the panel members received money directly from drug companies, including Cephalon. Dr. Luis E. Fayad, a hematologist at the University of Texas MD Anderson Cancer Center, is one such panel member who reported receiving $97,750 from Cephalon in 2009 for service on "advisory boards, speakers bureau, expert witness, or [as a] consultant."

75. NCCN acknowledges that it (not just its panel members) receives "support from many companies" and lists 33 drug manufacturers on its "corporate council." It lists 25 drug company supporters (including Cephalon) on its website, but does not identify the amounts of

their donations. However, NCCN's 2009 Annual Report discloses that Cephalon contributed almost $1.4 million to NCCN in 2009 for clinical studies of Treanda®. *See* NCCN Annual Report 2009 at p.18, *available at*, www.nccn.org/about/pdf/annual_report.pdf (last visited Aug. 17, 2010). It therefore was not a surprise when Cephalon announced in early 2010 that the NCCN Guidelines would support the off-label use of Treanda® in the front-line treatment of iNHL—a financial coup for Cephalon. *See* Cephalon, Inc., Annual Report (Form 10-K) (Feb. 12, 2010), *available at*, http://www.cephalon.com (last visited Aug. 17, 2010). No source is provided for the addition of iNHL to the NCCN Guidelines, nor do they reveal any influence by Cephalon.

76. NCCN recognizes the very real concerns with its independence arising from the large sums of money that panelists receive from drug makers like Cephalon. According to its own Conflict of Interest Policy:

> While corporate and industry involvement plays a growing role in the support of oncology research, the financial incentives that accompany such involvement may lead to conflicts of interest. NCCN also recognizes that the majority of NCCN Guidelines Panel Members have complex relationships with industry including conducting research in areas such as medical devices, diagnostics, drugs, and biologics. . . . [F]inancial conflicts of interest have the potential to introduce biases into the development process of NCCN Guidelines and NCCN Task Forces, thereby potentially affecting the integrity of the NCCN Guidelines or NCCN Task Forces.

77. In addition to the obvious problem posed by these financial conflicts of interest, there is increasing concern within the academic community about the scientific reliability of the citations contained in the oncology Compendia. One recent study concluded that the Compendia relied on by oncologists for up-to-date evidence and reimbursement information for off-label uses "lack transparency, cite little current evidence, and lack systematic methods to review or update evidence." *See* Abernethy, A.P., *et al.*, Systematic Review: Reliability of Compendia

Methods for Off-Label Oncology Indications, ANN. INTERNAL MED., 150:336-343 (2009) (the "Abernethy Study"). In fact, the Abernethy Study made several alarming findings, including the following conclusion upon the authors' review of fourteen off-label indications for cancer drugs that were cited in the Compendia:

> Cited evidence was scanty and inconsistent across Compendia, which raises questions about the processes by which evidence is identified and selected to generate recommendations, the potential biases or conflicts of interest that affect decisions of whether to include an indication or how to present the evidence, and the comprehensiveness and quality of the evidence that the Compendia include. . . . The evidence included in the Compendia we evaluated did not seem to be updated in a timely, regular, and explicit manner.

See Abernethy Study, *supra*, at 341. The authors also concluded:

> In addition to the limited number of research studies cited, the citations were often neither the most recent nor derived from the highest available level of evidence. All Compendia lacked explicit, systematic procedures for determining inclusion of off-label indications, and stated conditions for including non-FDA indications did not match actual practices of inclusion.

Id.

78. Further, Compendia staff cannot be assured of full access to all possibly relevant evidence, including complete evidence regarding a drug's potentially harmful side effects, and so another recent study concluded that the Compendia's use of unpublished or methodologically weaker evidence may have unpredictable effects on the ultimate validity of their recommendations. *See* Tillman, et al., "Compendia And Anticancer Therapy Under Medicare," ANN. INTERNAL MED., 150: 348-350 (March 3, 2009).

79. Pharmaceutical companies have contributed to the problems with the Compendia by, among other things, funding marginal studies and then foisting those studies onto the Compendia publishers. They do this because once the FDA has approved a single indication for a particular drug, it is far easier, quicker, and less expensive for the company to obtain

Compendia support for additional uses than it is to obtain FDA-approval for those additional uses. Drug companies like Cephalon "have a direct interest in maximizing the number of accepted indications that are listed in approved Compendia, and thus eligible for payment. Given this basic motivation, industry could be expected to favor policies that accept marginal data on a drug's effectiveness as evidence justifying reimbursement for that agent." *See* McKinney *et al.*, WHITE PAPER: POTENTIAL CONFLICT OF INTEREST IN THE PRODUCTION OF DRUG COMPENDIA; Agency for Healthcare Research and Quality (April 2009), *available at*, http://www.cms.gov/determinationprocess/downloads/id64TA.pdf (last visited Aug. 17, 2010).

80. Under these circumstances, the Compendia citations themselves cannot responsibly be taken at face value. Instead, they must be independently examined for indicia of scientific reliability and trustworthiness.

3. Using Oncology Group Purchasing Organizations to Drive Off-Label Sales

81. Cephalon understands that Group Purchasing Organizations ("GPOs") provide a malleable and corruptible entrée to promote its off-label message for Treanda® directly to physicians who might otherwise be reluctant to receive a sales pitch. Cephalon thus has deliberately used monies paid to oncology GPOs to further its Fraudulent Marketing Scheme for Treanda®.

82. GPOs are buying consortia or associations of hospitals and healthcare organizations designed to leverage the aggregate purchasing power of members by associating to negotiate contract terms with various suppliers of drugs, medical devices and other goods and services. *See* 21 C.F.R. § 203.3 (defining the term "group purchasing organization").

83. Over time, due to market forces and the significant financial opportunities presented, specialized GPOs developed to service oncologists. These oncology GPOs contract with networks of oncologists as part of strategic alliances. In addition to offering practice management and other services, the primary service these oncology GPOs offer is contracting for market differentiated pricing for oncology drugs from drug companies like Cephalon. By virtue of considerable industry consolidation, three primary GPOs have emerged as the dominant oncology GPOs through their contracted networks of oncologists: (i) ION, which is owned by drug wholesaler giant AmerisourceBergen, "controls" about 50% of the oncology market; (ii) US Oncology controls about 20% of the oncology market; and (iii) Onmark, which is owned by drug wholesaler McKesson, controls about 30% of the oncology market.

84. These oncology GPOs have developed their own proprietary "clinical pathways," which are step-by-step treatment protocols that include utilization of "preferred" oncology drugs in particular treatment contexts. These pathways are not limited to on-label uses of the specified drugs, so they offer the opportunity to grow off-label use if a drug is included. Not only is it in their financial best interests to do so (since the pathways drive sales to benefit oncology GPO oncologist participants), many oncologists rely on these clinical pathways to determine how they will treat their cancer patients, including whether and how they should prescribe drugs off-label. It thus is critical for companies like Cephalon to get their drugs onto these pathways. *See* Carlson, Bob, "*Controlling the Cost of Care Through Clinical Pathways*," Biotechnology Healthcare Vol. 6(1) (April 2009). As a result, these oncology GPOs wield significant influence in determining what oncology drugs, and at what cost, oncologists will use to treat their cancer patients.

85. As described more fully below, Cephalon understands that among the ways it can leverage its "return on investment" or "ROI" with these three oncology GPOs (in order to "pull through" additional off-label uses of Treanda®) include (i) paying for useless data at over-market prices; (ii) buying GPO disease management programs it neither needs nor wants; and (iii) sponsoring speaker programs, at a cost three times that of the fair market value (*i.e.*, so-called "In-Practice Programs") for affiliated oncologists where it features the off-label use of Treanda®.

B. TREANDA® FDA APPROVAL AND COMPENDIA SUPPORT

1. Background on Non-Hodgkin's Lymphoma and Treanda®

86. Non-Hodgkin's lymphoma ("NHL") refers to a group of cancers that affect the lymphatic system, most often starting in a single lymph node and then affecting lymphatic system organs like the spleen and tonsils. As the condition spreads, multiple lymph nodes may swell and other organs like the stomach may become affected. The condition tends to be classified into three types:

- Indolent (slowly-progressing) or low grade NHL (also called "iNHL");
- Aggressive or intermediate grade NHL; and
- Highly Aggressive or high-grade NHL.

Unlike lymph node swelling resulting from viruses or bacteria, lymph node swelling in NHL patients typically is not painful. Indolent (slowly-progressing) NHL is particularly difficult to diagnose because many people do not notice signs and symptoms until the disease is extremely advanced. Since iNHL progresses very slowly, it is possible for patients to live with the condition for many years.

2. Treanda® Has Only Limited FDA Approval and Inadequate Compendia Support

87. Treanda® is a derivative of mustard gas that was developed in Eastern Germany in the 1960's. It was approved by the FDA on March 20, 2008 for the treatment of patients with chronic lymphocytic leukemia ("CLL"). This initial approval came under the auspices of the Orphan Drug Act, which provides various financial incentives and market exclusivity for drug companies to develop drugs to treatments for rare diseases and conditions (*i.e.*, those that affect fewer than 200,000 persons in the U.S., or that affect more than 200,000 persons in the U.S. but for which treatment costs could not reasonably be expected to be recovered from sales). *See* 21 U.S.C. § 360bb(a)(2); 21 C.F.R. § 316.20(b)(8).

88. Later in 2008, Treanda® was approved for second- and third-line treatment of indolent B-cell non-Hodgkin's lymphoma ("iNHL"), which is iNHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. This indication also was approved under the Orphan Drug Act.

89. Thus, Treanda® is FDA-approved for only two indications: CLL, and the second- or third-line treatment of certain refractory iNHL patients who have tried (and failed) on prior oncology medications.

90. Support for Treanda® even within the notoriously unreliable Compendia has been thin and inadequate. Clinical Pharmacology supports the use of Treanda® in combination with rituximab for the front-line treatment of iNHL (thus nominally satisfying the first condition for Government Program reimbursement, discussed *supra*), but AHFS explicitly rejects that use on the basis that it "is not fully established because of inadequate data/experience." Thus, because Treanda® has been determined by AHFS to not be medically accepted for use in combination with rituximab for the front-line treatment of iNHL, it is not eligible for Government Program reimbursement.

3. Treanda®'s Orphan Drug Expiration In 2015 Causes Urgency to Begin Fraudulent Marketing Scheme

91. Importantly, the market exclusivity provided by orphan drug status is shorter than would be provided by typical patent protection, and thus Cephalon will lose market exclusivity for Treanda® in 2015. Cephalon's senior management has consistently identified Treanda®'s relatively short window of market exclusivity as a weakness, creating pressure to maximize sales as soon as possible, without waiting for the FDA to approve additional uses, including as front-line therapy for the treatment of iNHL.

92. This pressure to maximize sales as quickly as possible has led Cephalon to aggressively identify additional therapeutic uses for Treanda®. Thus, for example, Cephalon has sponsored studies to test Treanda®'s efficacy for the treatment of multiple myeloma, untreated high risk follicular lymphoma, ovarian cancer, and as a *front-line* treatment for iNHL (because its FDA approval is limited to second- and third-line treatment). In all, Cephalon has commissioned at least 29 studies since January 2004 to test the efficacy and safety of Treanda® for off-label uses, but its FDA approval remains limited to the initial two indications described *supra*.

93. As Treanda®'s approved indications are quite narrow, Cephalon has coveted the front-line market for the treatment of iNHL because that patient population is much larger than the on-label market that Treanda® is approved to treat. As described more fully below, Cephalon has illegally promoted Treanda® for use by that front-line market.

4. DDMAC Warnings Concerning Cephalon's Misleading Advertising of Treanda®

94. Cephalon has received at least two Warning Letters from the Division of Drug Marketing, Advertising and Communications ("DDMAC"), the division of the FDA charged

with overseeing the marketing and promotion of approved drugs to ensure advertisements are not false or misleading, provide a fair balance between the benefits and risk of the drug, and do not include off-label uses. The first Warning Letter, dated March 26, 2009, cited Cephalon for improperly promoting Treanda® through internet advertisements and sponsored links that were "misleading because they [made] representations and/or suggestions about the efficacy of [] Treanda, but fail[ed] to communicate *any* risk information associated with the use" of the drug. (Emphasis in original).

95. The second Warning Letter, dated December 18, 2009, cited Cephalon for improperly promoting Treanda® through dosing cards that omitted critical risk information, including that while Treanda® "is associated with numerous serious risks, some of which can be fatal[,]" the dosing card included only "an extremely limited risk presentation" that "omi[tted] critical details about the risks it disclose[d], including the context that some of these risks are frequent, severe and potentially fatal." As an example, DDMAC noted that while the dosing card did list myelosuppression as an "adverse reaction," it concealed the fact that in *two* NHL studies, 98 percent of patients experienced Grade 3-4 myelosuppression and two percent of patients died from myelosuppression-related adverse reactions. Likewise, although the dosing card did list "infections" as a possible adverse reaction, it concealed the fact that such infections had been associated with hospitalization, septic shock, and death. DDMAC concluded that Cephalon's "limited risk presentation" was "wholly inadequate to communicate the material risk information about Treanda, including risks that could potentially be ameliorated through interventions such as decreasing the dose or withholding treatment, and suggests that Treanda is safer than has been demonstrated by substantial evidence or substantial clinical experience."

5. Serious Side Effects Associated with the Use of Treanda®

96. There are numerous known serious side effects associated with the use of Treanda®. One of the known side effects of Treanda®, which is one among the various conditions listed on the drug's FDA label, is Stevens Johnson Syndrome ("SJS"). SJS is a debilitating condition, caused by an adverse reaction to certain medications, in which the skin burns from the inside out. Adverse drug reactions, such as SJS, account for approximately 150,000 deaths per year in the United States alone, making adverse drug reactions the fourth leading cause of death nationwide. Although SJS afflicts people of all ages, a large number of its victims are children.

97. In a 2009 filing with the U.S. Securities and Exchange Commission, Cephalon disclosed that it was aware that Treanda® was linked to at least two reported SJS cases that had progressed to the level of toxic epidermal necrolysis (TEN)—the more severe form of SJS, in which the skin lesions or burns cover more than 30% of the body. One of these two patients died as a result of the condition in December 2008. Despite acknowledging the serious, and fatal, adverse reactions associated with Treanda®, Cephalon has continued to promote the drug for uses that have not cleared the rigorous safety and efficacy evaluation process that precedes FDA approval.

C. CEPHALON'S FRAUDULENT MARKETING SCHEME FOR TREANDA®

98. Cephalon implemented its Fraudulent Marketing Scheme for Treanda® in order to capitalize on the market exclusivity provided by the Orphan Drug Act, and to expand the patient population for Treanda® beyond its FDA-approved limitations before it loses market exclusivity in 2015.

1. Pre-Launch: Getting the Off-Label Use Message Out

99. A key part of the off-label message for Treanda® began pre-launch, when Cephalon announced to oncologists and investors news concerning research being performed by Dr. Mathias Rummel. In October 2003, Dr. Rummel, of the University Hospital in Giessen, Germany, had initiated a study through the German Study Group for Indolent Lymphomas (the "StiL Group"). The study was designed to compare a combination of bendamustine (Treanda®) plus rituximab ("B-R") against a combination of cyclophosphamide, doxorubicin, vincristine, and prednisolone (commonly known as "CHOP") plus rituximab (collectively, "R-CHOP") for the front-line treatment of patients with advanced follicular, indolent, and mantle cell lymphomas. At the time, R-CHOP was—*and it remains*—the standard of care for front-line therapy of iNHL. This study soon came to be known as the "Rummel Study."

100. Even before the launch, Cephalon wanted both the oncology community and investors to know the message—use Treanda® to treat iNHL front line, even though Cephalon had not asked the FDA for this indication and even though the Rummel Study data were only preliminary. For example, at the annual American Society of Hematologists ("ASH"), (the world's largest and most influential professional society associated with the causes and treatments of blood disorders, including the cancers Treanda® is used to treat, and a group for which Cephalon is a "Gold Circle" corporate sponsor) meeting in 2007, the company on December 10, 2007 went so far as to hold an "earnings call" with investors to announce the good news that Treanda® was coming. The presenters to the investment community included Dr. Rummel himself, who told investors about his preliminary findings, which at the time were only preliminary, and Dr. Bruce D. Cheson from Georgetown University (himself a paid Treanda® consultant), who unabashedly discussed not just the Rummel Study, but the "competitive landscape" for Treanda®. Dr. Cheson told attendees that Treanda® "[s]hould rapidly be brought

to front-line" to treat iNHL and "[a]pproval by [the] FDA will certainly change the standard of practice in the US."

2. Treanda® Launch: The Fraudulent Marketing Scheme Begins

101. From the launch in early 2008, Cephalon used the Rummel Study as part of its off-label promotion of Treanda® front line. During a third quarter 2008 earnings call on October 28, 2008, CEO Frank Baldino told investors about the "exciting" results from the Rummel Study data that would be forthcoming at the ASH 2008 meeting:

> Over the next several months, you'll hear a lot of exciting information about TREANDA. . . .
>
> At the 50th Annual American society of Hematology meeting this December, we expect to see data from a number of clinical studies. In CLL, we expect data to be presented on TREANDA's use in combination with Rituxan in relapse patients. We also anticipate an update from Dr. Rummel[] on the [StiL Group] study of TREANDA use in first line NHL.

http://seekingalpha.com/article/102511-cephalon-inc-q3-2008-earnings-conference-call-transcript (last visited Aug. 22, 2010).

102. During a February 12, 2009 earnings call to announce the company's fourth quarter 2008 results, CEO Baldino told investors how Cephalon had begun to use the Rummel Study data to generate "enthusiasm" for Treanda®:

> [Treanda®] is [off] to a fantastic start.
>
> During the year, we called on over 7,000 oncologists, educating them about the benefits of TREANDA. In the first three quarters of launch, TREANDA recorded $14 million, $25 million and $36 million of sales, respectively.
>
> . . . In 2009, we expect the enthusiasm around TREANDA to continue through our clinical studies and the work of other investigators. One widely followed study is Dr. Rummel and the [StiL] Group's study of TREANDA's use in first line indolent NHL. At the December of 2008 ASH Meeting, Dr. Rummel provided interim look at this data with very encouraging results.

> We believe that the [StiL] Group will conclude this important study later this year. The feedback that we hear from the physicians is that TREANDA is easy to use, effective and relatively safe. Based on these key attributes we believe that adoption of this unique medication will continue to grow steadily.

Available at http://seekingalpha.com/article/120423-cephalon-inc-q4-2008-earnings-call-transcript (last visited Aug. 22, 2010).

3. May 1, 2009—The FDA Approves 25 mg Dose Vials of Treanda®, But Cephalon Withholds Them From the Market

103. Initially, Treanda® had been approved by the FDA only in 100 mg vials. However, it soon became clear that physicians wanted access to smaller volume vials, as the typical dose of Treanda® was only 72 mg, resulting in approximately 28 mg of wastage.

104. On May 1, 2009, the FDA approved the sale of 25 mg vials of Treanda® for use in connection with the previously-approved indications. Thereafter, Cephalon manufactured a significant quantity of 25 mg vials that could have been made available to oncologists. This should have led to less wastage in the use and reimbursement of Treanda®.

105. However, Cephalon knew that, if it made the 25 mg vials available to physicians, those physicians would purchase lower quantities of Treanda®, resulting in diminished revenues for Cephalon. Cephalon projected, in a July 2009 Integrated Business Plan, that launching the 25 mg vial would be a "downside" on the sales forecast for Treanda®, which would result in a 12%, or $19 million, loss of revenue.

106. At approximately the same time, Craig Phillips was promoted by Cephalon from National Sales Director to Vice President of Oncology and General Manager (replacing Liz Barrett, who had left in March 2009 to become President of Pfizer Oncology). He immediately became concerned that Cephalon would not meet its sales projections for Treanda® if it released the 25 mg vials to the market. So, Phillips (with CEO Frank Baldino's blessing) decided to keep the 25 mg vials in a warehouse until January 2010 *precisely because* doing so would force physicians to purchase—and Government Programs to reimburse—the larger, wasted volumes unnecessarily.

107. The Government Programs were not the only ones forced to overpay as a result of Cephalon's greed. By keeping the 25 mg vials in the warehouse between May 2009 and January 2010, Cephalon caused significant financial harm to Treanda® patients as well, because under Medicare Part B, patients must pay 20% co-insurance for infusion drugs. Thus, patients were forced to pay 20% of the unused, wasted portions of the 100 mg vials, when Cephalon could have made the less expensive option available to them.

108. When Cephalon finally did what it called internally a "soft launch" of the 25 mg vials on January 7, 2010 (vials that had been sitting for months in its warehouse), it did so quietly so that physicians would not learn of the less expensive, more efficient option for as long as possible. The motive was simple: profit. By forcing physicians to buy a 100 mg dose of Treanda® rather than using three 25 mg doses, Cephalon would earn more money.

4. December 5-8, 2009—The ASH 2009 Meeting, and the Introduction of the Final Rummel Study Data

109. Finally, in advance of the Rummel Study results (which were going to be presented at ASH 2009), Cephalon told investors at the UBS Global Life Sciences Conference on September 21, 2009 that the "iNHL data [would] be published soon" and to "[e]xpect substantial new data at ASH 2009." *See* http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MzUyMDk1fENoaWxkSUQ9MzQyMDA2fFR5cGU9MQ==&t=1 (last visited Aug. 22, 2010).

110. The final Rummel Study included 549 symptomatic patients, with a median age of 64, enrolled at 82 different centers. Histologies were distributed equally between B-R and R-CHOP. Of the 549 enrolled patients, 513 were evaluated for toxicity and efficacy.

111. The official results of the Rummel Study were announced at the ASH 2009 conference on December 5, 2009. Just three days prior, Cephalon CEO Baldino had purchased 80,000 shares of Cephalon stock at $56.07 per share, and less than a week after the announcement, Baldino purchased an additional 41,000 shares at a stock option price of $27.63 per share.

112. During his ASH 2009 presentation, Dr. Rummel proclaimed that the bendamustine/rituximab combination "has the potential to become a new standard first-line treatment option for patients" with iNHL.

113. However, despite the enthusiasm, there were significant limitations to the Rummel Study. First, it was not conducted as an FDA registration trial, and thus it did not follow the protocols for such trials. Thus, it likely could not be the foundation of an FDA approval for Treanda® for the front-line treatment of iNHL. Second, there were significant concerns about the fidelity of the data and the manner in which it was collected. Typically, when data for an FDA registration trial is collected from multiple centers (82 in this case), the study authors utilize intricate computer technology to ensure the validity of the results. In the Rummel Study, however, results were collected anecdotally and transferred onto an MS-Excel spreadsheet by Dr. Rummel and colleagues—inviting human error and misinterpretation.

114. Perhaps recognizing the inherent flaws of the Rummel Study, in April 3, 2009 Cephalon commissioned its own clinical trial through the Eastern Cooperative Oncology Group ("ECOG") in order to support the front-line use of Treanda® for the treatment iNHL. *See* "Study of Bendamustine Hydrochloride and Rituximab (BR) Compared With R-CVP or R-CHOP in the First-Line Treatment of Patients With Advanced Indolent Non-Hodgkin's Lymphoma (NHL) or Mantle Cell Lymphoma (MCL)," (the "BRIGHT Study"), *available at*, http://clinicaltrials.gov/

ct2/show/NCT00877006?spons=%22Cephalon%22&spons_ex=Y&rank=6 (last visited Aug. 22, 2010).

115. Based on Cephalon's internal estimates for the BRIGHT Study, the clinical trial will cost $60 million and is scheduled to be completed in October 2011. The company would soon thereafter submit its sNDA for the use of Treanda® in the front-line treatment of iNHL. According to this timeline, Cephalon projects that it would receive FDA approval for iNHL front line in March 2012.

5. Post-ASH 2009: The Presentation of the Final Rummel Study Results and Cephalon's Fraudulent Marketing Scheme Grows

116. Recognizing that front-line treatment of iNHL presented a significant financial opportunity for Cephalon, senior management accelerated the Fraudulent Marketing Scheme immediately following the release of the final Rummel Study data at ASH 2009.

117. During the week of December 14-18, 2009, Cephalon's Marketing Department held a WebEx seminar to train its Treanda® sales force on the new Rummel Study data. While the training ostensibly was "for educational purposes only," the instruction to the sales force was clear: Begin promoting the Rummel Study as a basis for physicians to prescribe Treanda® for front-line treatment of iNHL, notwithstanding the lack of FDA-approval and despite the serious flaws inherent in the Rummel Study data.

118. Another Post-ASH 2009 strategy employed by Cephalon was to use bogus market research studies to get the off-label message out to physicians. For example, shortly after the December 2009 ASH conference at which the final Rummel Study data were presented, Cephalon recruited 100 oncologists and hem-oncologists based on the number of *newly diagnosed* (*i.e.*, potential front-line) iNHL patients they treat to participate in a survey that

ostensibly was focused on their practices and prescribing habits. Physicians were paid between $300 and $500 to complete a "Dynamic Practice Simulation Questionnaire" that included 75 questions, many of which focused on the Rummel Study and the unapproved use of Treanda® as a front-line treatment for iNHL. By requiring that at least 30 of the 100 physicians polled to have attended the ASH 2009 conference, Cephalon was able to gauge the effectiveness of the off-label message at the conference, and at the same time promote the off-label message to physicians who did not attend the conference. The questionnaire plainly was an effort to promote the off-label Rummel data to these carefully-selected physicians in a captive context and while they were being paid for their time.

6. Cephalon's Improper Use of Continuing Medical Education Programs to Promote Treanda® for Off-Label Use

119. Another post-ASH 2009 tactic employed by Cephalon was the improper manipulation of continuing medical education ("CME") programs to use the Rummel Study data to promote the off-label use of Treanda® in the front-line treatment of iNHL.

120. Cephalon knows that CME courses are supposed to be fair, balanced, scientifically rigorous and free of commercial bias. *See* Guidance for Industry-Supported Scientific and Educational Activities, U.S. Department of Health and Human Services Food and Drug Administration Office of Policy, Nov. 1997, *available at*, http://www.gwumc.edu/cehp/pdf /CMEPolicies/FDAguidance.pdf (last visited Aug. 17, 2010). Off-label discussion is permitted only where the CME is free from commercial influence. *Id.*; *see also* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,738 (May 5, 2003) (addressing limits of proper drug company behavior relating to CMEs).

121. Nevertheless, Cephalon used CMEs illegally to promote the final Rummel Study data and its off-label message. In fact, the plan had been conceived even before the final Rummel Study data were announced. In a July 24, 2009 presentation of its Integrated Business Plan for oncology, Cephalon acknowledged that using CMEs as promotional vehicles for the off-label use of Treanda® was prohibited, and the Treanda® Brand Team described as "threats": (i) "CME Guidelines," which require CME presentations to be fair, balanced, scientifically rigorous and free of commercial bias; and (ii) "government restrictions on promotional practices."

122. But, the Cephalon plan was to use CME events to promote Treanda® off-label. During the same presentation, the Brand Team identified several priorities in its effort to "establish Treanda as the cornerstone of chemotherapy in hematologic disease," and they included the need to "satisfy unmet education need with CME" and to "explore new data dissemination opportunities." Of course, the only "new data" was the off-label Rummel study data.

123. Now, with the final Rummel Study results in hand, the plan was to use CMEs to promote the use of Treanda® in the front-line treatment of iNHL. For example, a CME program at ASH 2009 itself, during which the final Rummel Study results were announced, was moderated by Richard Van Etten, Chief of Hematology/Oncology and Director of the Cancer Center at Tufts Medical Center. Van Etten was no stranger to Cephalon or its desire to promote the off-label use of Treanda® for the front-line treatment of iNHL. In August of 2009 he had revealed a financial relationship with Cephalon in the context of a CME he moderated on hematological malignancies, and on December 1, 2009 (prior to the ASH Conference), he wrote that the off-label bendamustine/rituximab combination "looks as if it will become a standard" in

the front-line treatment of iNHL. He also provided a preview of the ASH 2009 conference to frequent CME provider Medscape.

124. Van Etten's enthusiasm for the off-label use of Treanda® was again apparent during an interview he gave after the ASH 2009 conference, portions of which were published by Medscape on December 9, 2009. During the interview, Van Etten provided the "buzz" Cephalon's Marketing Plan intended—*i.e.*, that the Rummel Study presented "potentially practice-changing data" and that, although he wanted to see "a confirmatory study" and "overall survival results," he did not "think we need to wait for that." There is no indication that Dr. Van Etten disclosed his Cephalon financial ties either when he made these remarks to Medscape, nor at the ASH 2009 conference. His relationship with Cephalon was thus never disclosed either to ASH attendees or to Medscape readers, leaving the appearance that his enthusiasm for Treanda® was spontaneous and not the result of any undue influence of any kind from the drug maker.

125. Following the ASH 2009 conference, Cephalon significantly expanded its use of CMEs to promote the off-label message for Treanda® by shifting the emphasis of its promotional activities from speaker programs (which many physicians intentionally avoid) to CME programs (which physicians attend in order to fulfill their CME requirements and because they are supposed to be free from drug company promotional influence).

126. To fuel the CME promotional buzz, early in 2010 (just weeks after the release of the Rummel Study data at ASH 2009), Craig Phillips, Vice President for the Oncology Business Unit, transferred $2 million from Cephalon's budget for the Sales & Marketing Department (which oversees speaker programs) to the budget for the company's Medical & Scientific Affairs Department (which oversees CME programs). Not only is it highly irregular for CME monies to come from the Sales & Marketing budget, it is clear that Phillips' plan (which was later approved

by Cephalon's Executive Committee) was intended to facilitate even greater off-label promotion of Treanda® based on the newly released Rummel Study by focusing the promotion on a larger, captive audience.

127. As might be expected, Cephalon Oncology sales representatives complained that shifting funds from speaker programs to CMEs would take away speaker monies they could use to promote the Rummel data. If the CMEs were intended to be operated legally as only objective educational events, their concern may have been valid. That was not the plan. VP Phillips would justify the use of CMEs by explaining that national CMEs were being used to promote off-label sales of Treanda® in numbers greater than would smaller-scale promotional speaker programs, and thus they would have a much better return on investment ("ROI") than would the speaker programs. Even though CMEs are not to be promotional, Cephalon knowingly used them as marketing vehicles and calculated revenues generated ("ROI") directly from these programs accordingly.

128. Cephalon used the $2 million to fund a series of CME courses that promoted the off-label use of Treanda®. For example:

(i) Drs. Bruce Cheson and John Leonard (both paid Cephalon consultants) used the Rummel Study data to promote the off-label use of Treanda® for the treatment of follicular lymphoma in a CME entitled "2009 ASH Update on Hematologic Malignancies: Indolent Lymphoma," which was posted on February 2, 2010.

(ii) Dr. Rummel himself led a Cephalon-sponsored CME course in which he stated that Treanda® plus rituximab likely would likely be "the treatment of first choice" for front-line iNHL. In the CME, entitled "Improving the

Care of Your Patient with NHL: An International Visiting Professor Program," Dr. Rummel (who disclosed he received "consultant fees" from Cephalon) told the audience that the B-R regimen is the standard treatment in Germany because it has been approved for that use in Germany for many years. Dr. Rummel then announced that in Germany's healthcare system, "*all*" German private practitioners use Treanda® in the front-line treatment of iNHL, thereby encouraging the attendee physicians to do the same, the absence of FDA approval notwithstanding.

(iii) Dr. Jonathan W. Friedberg—another recipient of Cephalon research grants—advocated the off-label use of Treanda® for the treatment of both follicular lymphoma and mantle cell lymphoma in a quasi-CME article entitled "Managing High-Risk Patients With Non-Hodgkin's Lymphoma: Two Cases," which was posted on April 13, 2010.

129. Cephalon's illegal strategy to manipulate CME courses into promotional events was still in full effect at the American Society of Clinical Oncology ("ASCO"), which was scheduled to hold a CME Satellite Symposium in Chicago from June 4-8, 2010, supported by an unrestricted educational grant from Cephalon.

130. At the end of May 2010, approximately one week before this supposedly educational symposium, Cephalon's Senior Director of Marketing, Matt Shaulis, spoke directly with Neil Love, owner of the CME provider "Research to Practice" and who was slated to moderate the symposium. Shaulis wanted to ensure that Love would include an appropriately favorable off-label message for Treanda® as front-line treatment for iNHL.

131. "Research to Practice" describes itself as a "medical education company . . . specializing in physician and allied health professional education focused exclusively on oncology and hematology." *See* http://www.researchtopractice.com/about-us (last visited Aug. 21, 2010). The company claims to provide "unbiased educational perspectives," but the influence that it allows Cephalon in its programs reveals rampant commercial bias.

132. In preparation for another recent "Research to Practice" CME entitled "Hematologic Oncology Update Think Tank 2010," Cephalon Marketing personnel provided "Research to Practice" the names of three key opinion leaders ("KOLs") as speakers who had proven to be strong proponents of an off-label message for Treanda®. Furthermore, Cephalon sent its Senior Product Manager, Alexandra Cherry, to attend the on-site recording of the CME program in Miami in order to provide input to the CME program as it was being recorded. Research to Practice was more than happy to accommodate Cephalon, because the drug maker had dedicated hundreds of thousands of dollars in 2010 to ensure a favorable, albeit highly improper, off-label message for Treanda®.

133. Cephalon's scheme to use CMEs as a vehicle to illegally promote the off-label uses of Treanda® violated applicable industry standards, FDA rules and regulations, as well as its own internal guidelines for conducting CMEs, all in an effort to increase its bottom line through the off-label sales of Treanda®. Cephalon has sponsored as many pro-Treanda® CME courses as possible, with Cephalon personnel ensuring that many courses promote the off-label use of Treanda® for front-line treatment of iNHL. Only *after* the $2 million had been transferred from the Sales & Marketing budget to fund CME events to promote Treanda® off-label did Cephalon erect a "firewall" between its Sales & Marketing divisions and its Medical and Scientific Affairs organization. But, the damage had been done.

134. And, despite removing $2 million from the speaker budget, Cephalon still managed to curry favor with key physicians by keeping more than 100 of them on its speakers' payroll. This enabled Cephalon to pay these physicians to complete speaker training and participate in product training. There they received on- and off-label information, *even though there no longer was funding to send them out to headline speaker programs*, since those funds had been funneled to off-label Treanda® CME programs instead. In essence, Cephalon had paid influential physicians to join a nationwide group of potential speakers who, though not being utilized as speakers, were armed with the company's off-label message and left to disseminate that message in their practices, as well as other interactions with others in the field of hematology.

7. Cephalon Uses Bogus Advisory Boards to Illegally Promote Off-Label Uses of Treanda® to Funnel Money to Doctors Who Treat Large Numbers of iNHL Patients

135. With the excitement generated from the Rummel Study growing (and facing a limited window of opportunity with the 2015 Orphan Drug expiration) Cephalon sought a mechanism by which to encourage physicians to prescribe Treanda® for off-label iNHL front-line use. To that end, Cephalon created so-called "Advisory Boards," which were comprised of doctors who were selected as candidates for the company's Fraudulent Marketing Scheme.

136. The Treanda® Advisory Boards were designed to appear to share scientific information between Cephalon and healthcare professionals with expertise in treating iNHL. In practice, however, these boards are thinly-veiled marketing events intended to promote off-label uses of Treanda® in the front-line treatment of iNHL.

137. Tellingly, the Advisory Boards are run by Cephalon's Marketing Department (not its Medical Affairs division), and physician attendees are nominated to attend by the company's

Sales and Marketing staff based on their potential to write large numbers of prescriptions for Treanda® in the treatment of iNHL-1. In this manner, a doctor can "earn" a deluxe vacation and an honorarium of up to $4,000 for the day simply to learn about the off-label prescribing opportunities for Treanda®. Thus, Cephalon uses the Advisory Boards as an incentive to encourage doctors to write off-label prescriptions for Treanda®.

138. Cephalon generally has conducted multiple Advisory Board meetings each quarter, and the meetings are often conducted at lavish locations. Rather than being intended to gather focus groups of 10-15 sample oncologists to whom Cephalon could present study results and engage in scientific interchange, the Advisory Boards have been unabashedly promotional. Some of the advisory boards had as many as 60 oncologist attendees, far more than necessary for such a focus group.

139. Lest there be any doubt about Cephalon's intent in the way it used the Advisory Boards, its Marketing Department carefully monitors the "return on investment" or "ROI." For example, a July 22, 2010 Treanda® Brand Review slide deck touts the "High Efficiency" of the Marketing efforts with an 8 to 1 ROI for the $826,000 in Advisory Board monies expended for the year to date.

8. Cephalon's Use of Oncology Group Purchasing Organizations to Disseminate the Off-Label Message About Treanda®

140. Another strategy that Cephalon has employed since the launch of Treanda® in 2008 was to expand the patient population for off-label, front-line iNHL treatment through the improper use of financial inducements to oncology group purchasing organizations ("GPOs") and their networks of member oncologists, discussed *supra,* to influence prescriber behavior. The three leading GPOs for Cephalon's scheme to grow the off-label use of Treanda® are:

- ION (which along with Oncology Supply comprise AmerisourceBergen Specialty Group, a division of the giant drug wholesaler, AmerisourceBergen),
- US Oncology; and
- Onmark (which along with P4 form McKesson Specialty Care Solutions, a division of another giant drug wholesaler, McKesson).

Even though Cephalon refers to these GPOs as "practice management organizations" or "PMOs" out of concern that relationships with GPOs might be considered illicit, they are still functionally oncology GPOs. The plan was to make the oncology GPOs partners with Cephalon in a "pay to play" scheme.

141. Cephalon knows that the oncology GPOs provide a significant opportunity to increase the patient population using Treanda® because of the influence they exert over prescriber behavior through their preferred pricing and clinical pathways. *See* discussion *supra*. Cephalon also knows that oncology GPOs can provide access to physicians who would not otherwise sit for a promotional pitch but will do so if required in order to remain eligible for the GPOs' preferred pricing programs. Thus, Cephalon has entered into special deals with the oncology GPOs to leverage their access and influence over physician behavior in order to advance its own off-label message. This GPO "pull through" effort has been a key component of Cephalon's Fraudulent Marketing Scheme for Treanda®.

142. One way that Cephalon buys preferential treatment from GPOs, and thus access to their physician members, is through financial inducements paid directly to the GPOs. Cephalon disguises the true purpose of these payments—calling them purchases for (unnecessary or redundant) services, such as data fees and disease management fees, or (excessive) speaker program fees (so-called "In-Practice Programs")—to conceal the appearance that they are bribes

or rebates for drug purchases by the GPOs or their members. The label is important because if the "purchases" were considered rebates, they would have a negative impact on the average selling price ("ASP") for Cephalon's drugs. In the case of injectable oncology drugs like Treanda®, ASP is the key metric used to determine how much the Government Programs will reimburse for each prescription. Hidden "rebates" through redundant data purchase fees, disease management fees, and above fair market value speaker program fees would lower the ASP, causing the Government Programs to pay an artificially inflated price to physicians who buy and bill for Cephalon's drugs.

143. As indicated, one purpose of Cephalon's payments to the GPOs has been to buy access to the oncology GPOs' members so that Cephalon can promote off-label uses of Treanda® directly to an otherwise reluctant audience. Indeed, one internal Cephalon presentation confirms that GPOs "provide [an] audience that is tougher to recruit." Thus, Cephalon pays the oncology GPOs for the right to sponsor "In-Practice Programs," which are off-label promotional pitches to the oncology GPOs' members. These oncologists and hematologists have little interest in sitting through an on-label discussion of a drug with which they are already familiar, but instead are more interested in the off-label uses. Cephalon is fully aware of this fact and its trained speakers often stray from the approved, on-label slides, and proactively discuss their personal experiences using Treanda® off-label, such as in the front-line treatment of iNHL.

144. And, Cephalon has accelerated its spending in this area following the release of the final Rummel Study data. For example, in just the seven months following release of the that data, Cephalon spent almost *$500,000* to fund the inflated cost of these In-Practice Programs for individual US Oncology member practices to expose them to the latest off-label data for Treanda®. For example, Cephalon paid US Oncology ("USO") $16,000 for *each* of these

programs—more than three times the cost of a traditional speaker program. The overpayment was no coincidence. In return, USO requires that, for each of its member physician practices, at least fifty percent of its physicians *must attend* four In-Practice Programs each year. Thus, Cephalon overpays USO for the ability to place its influential speakers (who are paid and fully trained in Cephalon's off-label messaging) in front of large, high prescribing oncology practices.

145. That Cephalon views these In-Practice Programs primarily as opportunities to drive off-label sales is confirmed by Cephalon Oncology's August 12, 2010 draft Integrated Business Plan, which included one slide entitled: "IPP: USO Programs Yield Positive ROI." The slide demonstrates how Cephalon's investment in funding 31 USO In-Practice Programs in 2010 provided to 189 physicians (just over six oncologists per program), at an average cost of $16,000 per program, has resulted in average annualized Treanda® sales growth of $420,000, or an incredible 12:1 "return on investment" related to the off-label message of using Treanda® to treat iNHL front line. The slide highlights seven particular oncology practices who are part of the USO network and the positive impact that off-label In-Practice Programs had on their Treanda® sales growth:

- Florida Cancer Institute had 105% growth monthly from $56,520 to $59,000;
- New York Oncology/Hematology had 169% growth monthly from $76,500 to $129,150;
- Longview Cancer Center had 161% growth monthly from $13,800 to $22,200;
- Northwest Connecticut Oncology-Hematology Associates had 267% growth monthly from $15,840 to $42,300;
- Rocky Mountain Cancer Centers had 143% growth monthly from $81,360 to $116,100;

- Oncology Hematology Associates had 152% growth per month from $75,600 to $115,200; and
- Texas Oncology had 100% growth from $0 per month to $84,150.

Clearly, the USO In-Practice Programs were driving home the off-label message for Treanda®.

146. Another implicit (if not explicit) *quid pro quo* for Cephalon's financial largesse is to influence the favorable treatment of Treanda® on the oncology GPO's pathways. An internal Cephalon Oncology Business Metric Review presentation dated December 16, 2009 set forth "Key Issues & Action plans" that included "improving Treanda® positioning in NCCN and PMO guidelines and pathways." One of the specific directives was to "engage decision makers in advisory dialogue," as well as "leverage clinical data, influencer relationships, and physician advocacy."

147. Funding follows closely, for the very next slide in the December 16, 2009 presentation explained that Cephalon intends to more than double its number of GPO Speaker Programs/In-Practice Programs from 28 in 2009, to 65 in 2010 and 95 in 2011. The *only* data being "leveraged" to this critical, captive audience was the new, off-label Rummel Study data.

9. March 1, 2010—Cephalon Accelerates Off-Label Promotion at Its Annual Oncology Sales Meeting

148. Cephalon reinforced the off-label promotional message to its Oncology Sales force at its 2010 Annual Sales Meeting in San Diego. The attendees at the March 1, 2010 meeting included 92 Oncology sales representatives, twelve area managers, two regional directors, and a number of senior management from Cephalon's headquarters. The purpose of the meeting was to introduce new promotional pitches, announce sales objectives for 2010, and build morale within the Sales force.

149. Craig Phillips, the Vice President for the Oncology Business Unit, began the meeting with some opening remarks (which typically are intended to create excitement for the upcoming year), announcing to the Sales force (nearly 150 sales representatives, district managers, and regional managers) that Cephalon was in a great position because of the "great new data" from the Rummel Study—even though the Rummel data related *only* to unapproved uses. Not surprisingly, Phillips' statement created excitement within the Sales force, which understood that Cephalon's (and thus their own) financial fortunes would rise if they were able to use the data to encourage oncologists to use Treanda® for the front-line treatment of iNHL.

150. Despite the explicit, off-label content of Phillips' remarks, no one at the meeting, including senior management that were in attendance, took corrective action to make clear that the off-label statement was improper and that it would be illegal to use the Rummel Study data to promote the off-label use of Treanda®.

10. May 10, 2010—Cephalon's Q1 2010 Earnings Call

151. By the Spring of 2010, Cephalon's scheme to use the Rummel Study off-label had begun to pay off. In a May 10, 2010 earnings call with investors, Cephalon CEO Baldino touted the company's recent success in promoting Treanda®:

> Growing acceptance by hematologists resulted in [Treanda®] sales of $81.3 million for the quarter. TREANDA continues to penetrate the market and is fast becoming an important treatment option for oncologists and patients. We are committed to advancing treatment for cancer patients by seeking FDA approval for TREANDA as treatment for front-line indolent NHL.

See Cephalon Q1 2010 Earnings Call, May 10, 2010, *available at*, http://seekingalpha.com /article/203028-cephalon-q1-2010-earnings-call-transcript (last visited Aug. 17, 2010). Of course, Baldino knew that virtually all the recent sales growth was attributable to the company's own off-label promotional efforts, because there was no other way to explain the recent upward

spike. Indeed, he went on in that same earnings call to state that Cephalon hoped to be able to use the Rummel Study to gain FDA approval for iNHL front line (even though Cephalon knew the study was fatally flawed), and that the company "remain[ed] confident that TREANDA's proven efficacy, safety and ease-of-use will allow us to reach additional patients *as physician's gain experience and confidence in its use*." *Id.* (emphasis added). Of course, any such use in the front-line treatment of iNHL, which explicitly was the focus of Baldino's remarks, would have been off-label.

11. June 2010—Senior Director of Oncology Sales Resigns When Internal Audits Reveal Treanda® Off-Label Promotion

152. As part of its settlement of criminal and civil charges relating to the off-label promotion of Actiq®, Provigil® and Gabatril®, Cephalon had agreed to perform internal audits to determine whether its promotional activities going forward were compliant with Federal law, and thereafter to report any further compliance issues, including off-label promotion, to the Government.

153. In 2010, Cephalon conducted two separate internal audits of its Sales force to determine what, if any, compliance issues existed within the company. As part of the audits, which were conducted by ZS Associates, Inc. from Evanston, Illinois, various healthcare providers were contacted and asked about their latest discussions with Treanda® sales representatives. The results of the audits revealed that Cephalon's sales representatives were consistently promoting Treanda® for off-label uses by discussing the front-line iNHL results from the Rummel Study.

154. Shortly after the results from the first audit were announced to senior management, Cephalon's Senior Director of Sales, Bruce Ward, resigned from the company in

June 2010. In his farewell email to the Oncology Business Unit and Sales Team, Ward wrote that senior management had been "extremely supportive of my leadership and [that he is] confident that the compliance issue we have faced will soon be a thing of the past." Of course, in light of its being under a Corporate Integrity Agreement, the compliance issues should *already* have been a thing of the past.

155. Cephalon recently made an effort to make it appear that it did not condone the off-label promotion by cutting sales representatives' bonuses by 25%. But, the bonus reduction was all "smoke and mirrors" and belied what was really going on, because off-label promotion has continued unabated. In 2009 the average sales representative had received a $75,000 bonus, equating to $18,750 per fiscal quarter. Cephalon announced it would cap the bonus reduction at $13,000, so the most the average sales representative stands to lose per quarter is a paltry $3,250. Sales representatives recognize this and have stated that it is in their financial interest to continue promoting Treanda® off-label even with the negligible bonus deduction because they can earn substantially more by promoting Treanda® off-label than if they only sold the drug only for on-label uses.

156. During a recent Cephalon manager's meeting held during the week of August 23, 2010, in Dallas, Texas, the Senior Director of Global Compliance, Karen Lowney, announced to the sales managers that the internal audits performed by ZS Associates were purposely designed not to break down the data collected to the level of sales representatives. By keeping the results at a macro level, individual representatives who are promoting Treanda® off-label are thus not being singled out and fired. Cephalon's calculated strategy (at the compliance-level, no less) of identifying the extent of its off-label promotional efforts, while at the same time intentionally

insulating sales representatives from the consequences thereof, confirms the corporate-wide commitment to its Fraudulent Marketing Scheme.

12. July 22, 2010—Cephalon's CEO and Executive Committee Support Off-Label Use of Treanda® During a Treanda® Brand Review Meeting

157. The emphasis on off-label sales growth rises to the top of the company. Even though the company's official position was that it was pursuing FDA approval for the use of Treanda® as front-line treatment for iNHL, as recently as July 22, 2010, CEO Baldino questioned the economic wisdom of such efforts during private meetings with senior management. During the July 22, 2010 Treanda® Brand Review meeting among senior executives (including Baldino, the entire Executive Committee, multiple Vice Presidents from Clinical Development, and CFO Wilco Groenhuysen), the Senior Director of Marketing, Matt Shaulis, delivered a presentation of Treanda®'s off-label market growth in the treatment of front-line iNHL.

158. At the conclusion of Shaulis' presentation, Baldino asked whether Treanda® already was being widely reimbursed by Government Programs and private insurers as a front-line therapy for iNHL despite the lack of FDA approval. When VP Craig Phillips stated that it was, Baldino asked how much more market share Cephalon might gain if it were to receive FDA approval for that use. Phillips deferred to Cephalon's Senior Director of Strategic Analysis, Vlad Vitoc, who stated that Cephalon stood to gain "around 5 percent to 8 percent" of additional market share if it obtained FDA-approval for front-line treatment of iNHL.

159. Upon hearing this, Baldino questioned Cephalon's plans to continue enrolling patients in its BRIGHT Study, the sole purpose of which was to confirm the Rummel Study data. Baldino queried why, at a cost of roughly $60 million, would Cephalon expend such resources to

obtain only marginal market growth when the company was "already doing well in the off-label, front-line iNHL market." Nobody in the room provided a response.

160. It was clear that the plan was to make public statements about conducting the BRIGHT Study while Cephalon simultaneously continued its off-label efforts.

D. THE FRAUDULENT MARKETING SCHEME FOR TREANDA® HAS BEEN A FINANCIAL BOON FOR CEPHALON

161. Cephalon's fraudulent marketing efforts have paid off. Numerous internal documents reveal sizeable spikes in sales of Treanda® first, when the interim Rummel Study data was leaked in December 2008, and then again in late 2009 when final Rummel Study data was leaked just prior to the ASH 2009 conference.

162. Internal Cephalon documents also reveal that, while the per-patient cost to complete a course of Treanda® treatment with the standard-of-care R-CHOP protocol is only $21,855, the estimated per-patient cost to complete a course of treatment with the off-label, unapproved Treanda®/Rituxan® regimen that Cephalon has been promoting is almost three times as much—$58,269. Thus, not only has Cephalon succeeded in increasing its own revenues, it has caused Government Programs to pay nearly three times as much per patient as they would have paid had the on-label standard-of-care treatment been prescribed. In addition, the cancer patients (and their families) are also being required to pick up the increased coinsurance associated with the more expensive treatments.

163. Not surprisingly, the off-label scheme has resulted in dramatic increases in Treanda® sales. On July 27, 2010, Cephalon announced record sales and earnings in the second quarter of 2010. During that period, oncology sales were $129.9 million, reflecting a 58 percent increase over the same period the prior year "due to strong sales of Treanda®." Barring a change

in the way Cephalon does business, analysts project even greater growth. Oppenheimer & Co.'s Brett Holley predicts that sales of Treanda® for NHL and CLL will peak at $700 million, with about $300 million of that total coming from the off-label, front-line treatment of iNHL. Piper Jaffray & Co.'s David Amsellem projects that the off-label Rummel Study data is likely to make Treanda® Cephalon's top-selling drug, suggesting that it is not "beyond the realm of possibility" that Treanda® could become a "blockbuster agent" with up to $1 billion in peak sales.

164. Cephalon's Fraudulent Marketing Scheme for Treanda® is ongoing. Indeed, an internal Integrated Business Plan presentation in August 2010 confirmed that one of Cephalon's "Sales & Marketing Keys to Growth" is to "Optimize [the] Front-Line Label Opportunity" for Treanda®.

VII. THE FRAUDULENT MARKETING SCHEME FOR FENTORA®

165. The fraudulent marketing scheme for Fentora® had its seeds in Cephalon's off-label promotion of its predecessor drug Actiq®, a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge. Actiq® initially had sales in the tens of millions, but as a result of Cephalon's illegal, off-label marketing, by 2006 sales exceeded $500 million dollars.

166. Actiq® had been approved in 1999 by the FDA for the very limited purpose of treating breakthrough pain in cancer patients who were "opioid tolerant." Breakthrough pain ("BTP"), a component of chronic pain, is a transitory flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/day, at least 25 mcg of transdermal fentanyl/hr, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

167. There is no safe dose of Actiq® in patients that are not opioid tolerant. Fentanyl, a key ingredient in Actiq®, has been linked to fatal respiratory complications in those patients, and Actiq® was associated with the reported deaths of 127 people and another 91 FDA reported incidents of severe side effects.

168. The widespread off-label use of Actiq® caused the FDA's Office of Criminal Investigations and the U.S. Attorney for the Eastern District of Pennsylvania to investigate Cephalon's marketing of the drug. The Government found that from 2001 through at least 2006, Cephalon promoted Actiq® off-label for such maladies as migraines, back pain, and even injuries. The investigation also found that Cephalon had structured its sales quotas and bonuses in such a way that sales representatives could only reach their goals if they sold the drug for off-label use.

169. In order to replace the revenue stream it had enjoyed from the off-label promotion of Actiq® (which would lose patent protection on September 28, 2006 when the first generic forms came to market), Cephalon purchased a new opioid drug, Fentora®, from Cima Labs and subsequently submitted an NDA for the drug in August of 2005.

A. BACKGROUND OF FENTORA® AND BREAKTHROUGH CANCER PAIN

170. Fentora® (fentanyl citrate buccal tablet) is a potent opioid analgesic that is formulated as a flat-faced, round, beveled edge white tablet. It is intended for buccal mucosal administration, *i.e.*, it is placed and retained within the mouth for a period sufficient to allow disintegration of the tablet and absorption of fentanyl across the oral mucosa.

171. Fentora® is a very dangerous drug. Its primary ingredient, fentanyl, is a pure opioid agonist whose principal therapeutic action is analgesia. Other members of the class known as opioid agonists include substances such as morphine, oxycodone, hydromorphone,

codeine, and hydrocodone. Pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, cough suppression, and analgesia.

172. Fentora® was approved by the FDA on September 25, 2006 for the treatment of breakthrough cancer pain ("BTCP") in cancer patients who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. There are no other FDA approvals for Fentora®, and the Compendia do not support any other uses of Fentora®.

173. The danger inherent in *any* prescription for Fentora® is confirmed by the unusually strong and detailed Black Box Warning that the FDA has required be included on its label. The warning reads:

> **Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdosing.**
>
> ***FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.**
>
> ***FENTORA* is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients.**
>
> **When prescribing, do not convert patients on a mcg per mcg basis from Actiq® to *FENTORA*. Carefully consult the Initial Dosing Recommendations table. (See DOSAGE AND ADMINISTRATION, Table 7.)**
>
> **When dispensing, do not substitute a *FENTORA* prescription for other fentanyl products. Substantial differences exist in the pharmacokinetic profile of *FENTORA* compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of *FENTORA* for any other fentanyl product may result in fatal overdose.**

> Special care must be used when dosing *FENTORA*. If the breakthrough pain episode is not relieved after 30 minutes, patients may take ONLY one additional dose using the same strength and must wait at least 4 hours before taking another dose. (See **DOSAGE AND ADMINISTRATION**.)
>
> ***FENTORA* contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. *FENTORA* can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing *FENTORA* in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.**
>
> **Patients and their caregivers must be instructed that *FENTORA* contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all tablets out of the reach of children. (See Information for Patients and Caregivers for disposal instructions.)**
>
> ***FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.**

(Emphasis in original).

174. BTCP is a pain syndrome in its own right, and it is not the result of under-treated background pain. While inadequate doses of around-the-clock medication may be responsible for some cancer pain flares, BTCP can occur even when a patient is taking the correct dose of medication on a regular schedule to control background pain. Because the nature of BTCP differs from that of background pain, it requires a unique treatment approach.

B. THERE ARE NO OFF-LABEL, COMPENDIA-SUPPORTED USES FOR FENTORA®

175. As stated *supra*, the only way a prescription for an off-label use can be reimbursed under Medicaid, Medicare, or the other Government Programs is if the particular off-label use has been approved by one of the compendia identified in the Social Security Act, such approval qualifying the use as a "medically accepted indication."

176. In both the leading and most commonly available statutorily approved Compendium for non-oncology drugs, DrugDex and AHFS, there are currently no off-label, Compendia-supported uses for Fentora®.

C. THE FRAUDULENT MARKETING SCHEME FOR FENTORA®

1. October 1, 2006—The Launch of Fentora® and Off-Label Promotion Begins

177. Cephalon launched Fentora® on October 1, 2006, and the fraudulent marketing scheme was implemented on the first day. Although the market for Fentora®'s only on-label treatment—BTCP—is quite limited, Cephalon's fraudulent marketing scheme was both simple and immediately effective. Instead of using its oncology sales force to promote Fentora® on-label to the oncologists who treat the relatively small population of BTCP patients, Cephalon utilized its general pain sales force to promote Fentora® off-label to the pain specialists who treat a wide array of pain conditions—but generally not BTCP.

178. Specifically, from the first day, Cephalon used the same 100 general pain sales representatives who previously had been selling Actiq® to now sell Fentora® to the same physicians to whom they had been selling Actiq®, even though there could be no legal basis upon which to promote Fentora® to a physician who does not treat cancer patients.

179. In fact, Cephalon's pre-launch activities had "primed the market" for Fentora®, and its marketing materials were ready within weeks of the FDA approval. Also within weeks of the launch, Cephalon had trained numerous key opinion leaders in pain management to lead promotional programs for Fentora®, typically including off-label uses for the drug. Cephalon's basic message was that Fentora® was a major advance that offered a significant upgrade in the treatment of breakthrough pain (not breakthrough cancer pain) from Actiq®. Of course, this

substitution of Fentora® for Actiq® is exactly what the Black Box Warning on Fentora®'s label warns against. *See* discussion *supra*.

180. The plan to launch Fentora® by cannibalizing sales of Actiq® was a success, and on February 12, 2007, only five months after the launch, CEO Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come."

See http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (last visited Aug. 23, 2010). His choice of words was stunning, insofar as Cephalon could not utilize Fentora® to "retain" the Actiq® market without going off-label.

181. And just seven months post-launch, Cephalon's then Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts on May 1, 2007 about the company's successful and "aggressive" off-label launch, promoting Fentora® just as it had promoted Actiq®, *i.e.*, for non-cancer breakthrough pain:

> Prior to the launch of FENTORA, our pain care sales force had been detailing ACTIQ pretty broadly to about 17,000 physicians[;] however[,] a relatively small fraction of these physicians, about 2,000, were responsible for 80% of ACTIQ Prescriptions. It was these physicians who formed our primary target audience during the initial phase of launch.
>
> It is important to recognize that we did not embark upon a patient switch strategy. Our goal was to change prescribing habits of these high prescribing opioid physicians by educating them about the real benefits of FENTORA. In a crowded market, with numerous short and long acting opioid it was critical for us to get the docs attention and create sufficient awareness for our new product.
>
> Our pre-marketing efforts began in mid 2006 and by the end of March of 2007, we had detailed over two thirds of those 2,000 core physicians five times or more. This is a resulted in an unaided awareness for FENTORA among this group of over 50% and aided awareness of nearly 100%.

During the first quarter of 2007, we continue to focus on these core physicians and also began reaching out to the next tier of about 5,000 doctors who are high prescribers of opioids but who have not historically prescribed ACTIQ, and now as we enter May we are reaching out to all of those 17,000 targeted physicians and building our business across-the-board.

Two major opportunities are before us. One, is to continue growing FENTORA by educating physicians on the concept of breakthrough cancer pain and its treatment with rapid onset opioids. We've been at this now for almost seven years but still it remains a relatively poorly defined field.

The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. Let me first talk about breakthrough pain and rapid onset opioids.

While most investors [...] who follow Cephalon are pretty familiar with the concept of breakthrough pain, it's ironic to think that you [financial analysts] may be better informed than much of the physician community here in America. The truth is that breakthrough pain is a condition generally recognized only by top tier opioid prescribe[r]s and pain specialists that we typically call on. . . .

In addition, of course patients are generally not familiar with the term. As for the term rapid onset opioids, it is equally misunderstood by most physicians who perceive all short acting opioids as having rapid onset, which in most cases is simply incorrect.

The truly unfortunate result of all of this confusion is that physicians will usually just increase the dose or the frequency of a patient's short acting or long acting product when trying to treat the breakthrough cancer pain episodes. . . .

We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication.

As we advance our clinical work in non-cancer pain, we have a tremendous opportunity with FENTORA. When it comes to these non-cancer pain patients, the prevalence and characteristics of their breakthrough pain is very similar to that experienced by patients with cancer.

Estimates show that between 64% and 89% of patients with cancer pain experience breakthrough episodes, and about 74% of non-cancer pain patients experience these same breakthrough pain episodes. The groups are obviously very similar. In addition, time to peak intensity and the duration of the pain episode is similar for the two groups.

> Opioids are widely used in the treatment of these non-cancer patients. Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.

See http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript (last visited Aug. 23, 2010). Roche resigned from Cephalon in January 2010 to "pursue other longstanding interests."

182. Thus, while the FDA had approved Fentora® only for the treatment of BTCP in patients who already are receiving and are tolerant to opioid therapy, Cephalon's most senior executives brazenly acknowledged that, from the start, the company had set out to promote Fentora® for off-label uses.

2. September 26, 2007—The FDA Issues a Public Health Warning for Fentora®

183. On September 26, 2007, the FDA issued Public Health Advisory on Fentora® because it had received reports of deaths and other serious side effects related to its use. The FDA warned that Fentora® should be prescribed only for approved conditions and that dosage guidelines should be carefully followed.

184. This was not news to Cephalon, which earlier that month, on September 10, 2007, had sent similar warning letters to physicians. Cephalon's letter stated:

> We have recently learned of serious adverse events, including deaths in patients treated with *FENTORA*. These deaths occurred as a result of improper patient selection (*e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution.

That was a sanitized version of the truth since Cephalon's own deliberate marketing activities had much to do, for example, with any "improper patient selection."

185. In fact, the FDA Advisory had warned that several Fentora®-related deaths had occurred in patients who were prescribed the drug for off-label use. The FDA Advisory warned that Fentora® should not be used for any off-label conditions, including migraines, post operative pain or pain due to injury, and that it should be given only to patients who have developed opiate tolerance. The FDA also warned that other Fentora® deaths had been caused by doctors who prescribed higher-than-recommended doses of the drug. The FDA Advisory stated that Fentora® contains a much greater amount of fentanyl than other opiate painkillers, including Actiq®, and that Fentora® therefore was not a suitable substitute for these other painkillers.

3. May 6, 2008—The FDA Rejects the Request for Expanded Approval of Fentora®

186. The following year, the FDA convened a Joint Meeting on May 6, 2008 of its Life Support Drugs and Drug Safety and Risk Management Advisory Committees to discuss Cephalon's sNDA for expanded approval of Fentora® to treat non-cancer breakthrough pain. In support of its application, Cephalon had *admitted* that Fentora® already was being heavily prescribed for non-cancer pain:

> Among the patients with non-cancer-related BTP, there is general dissatisfaction with the most commonly used treatments (*i.e.*, short-acting oral opioids) because of their inadequate onset of effect. It is also known that substantial use of FENTORA, and its predecessor ACTIQ®, has been in the management of BTP in opioid-tolerant patients with chronic non-cancer pain. Taken together, these data point to the need for a medication for the effective treatment of patients with these painful conditions having an approved indication to do so.

See Joint Meeting: Anesthetic and Life Support Drugs, Advisory Committee and Drug Safety and Risk Management Advisory Committee, May 6, 2008, *available at*, http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (last visited Aug. 17, 2010). Cephalon acknowledged that "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of BTP in patients with chronic persistent non-cancer-related pain." *Id.*

187. At the Joint Meeting, the FDA presented data showing that 95 percent of all Fentora® use was for the off-label treatment of non-cancer pain. *See* Review of Fentora® and Actiq® Adverse Events from the Adverse Event Reporting System ("AERS") Database, May 6, 2008, *available at*, http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations.ppt#289,1 (last visited Aug. 17, 2010).

188. By an overwhelming vote (17-3), the relevant Advisory Committee voted against recommending approval of Cephalon's sNDA for Fentora®. The FDA responded to Cephalon on September 15, 2008, and requested that Cephalon implement, and demonstrate the effectiveness of, proposed enhancements to the Fentora® risk management program. Not long after, in December 2008, Cephalon received a supplemental request from the FDA, requesting that the company submit a Risk Evaluation and Mitigation Strategy (the "REMS Program") for Fentora®.

4. March 26, 2009—DDMAC Warning Concerning Cephalon's Misleading Advertising of Fentora®

189. Unburdened by the limits of the law and the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora® off-label to pain specialists as an upgrade over Actiq® for the treatment of non-cancer BTP—instead of on-label to oncologists for the treatment of BTCP alone. And Cephalon continued to promote Fentora® for use by all

cancer patients suffering BTCP, not simply those who already are receiving and are tolerant to opioid therapy for their underlying persistent pain.

190. It thus could not have been a surprise to Cephalon when it received a DDMAC Warning Letter, dated March 26, 2009, which warned that the company's promotional materials for Fentora® essentially amounted to off-label promotion of the drug. Specifically, the Warning Letter asserted that an internet (*i.e.*, direct-to-patient) advertisement was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain in a candidate for Fentora therapy . . . *when this is not the case*." (Emphasis added). DDMAC emphasized that Fentora®'s label approval was limited to cancer patients with breakthrough pain "**who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.**" (Emphasis in original). DDMAC explained that the misleading nature of the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original).

191. DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora® on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora [], but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original). This was particularly troubling because Fentora®'s FDA-approved label includes a Black Box Warning. *See* discussion *supra*.

5. Cephalon Has Continued to Knowingly and Illegally Promote Fentora® for Off-Label Uses

192. The focus on promoting Fentora® off-label to physicians who do not treat BTCP was not limited to the immediate post-launch period. Instead, Cephalon has continued to use its general pain sales force (which now numbers 110) to promote Fentora® to general pain specialists, instead of using its oncology sales force to promote Fentora® to oncologists, who are the physicians who treat BTCP.

193. Cephalon *knows* that its Fentora® promotions are not focused on the physicians who treat BTCP. Indeed, Cephalon recently commissioned several market research studies to determine whether there is "adequate" market potential to promote Fentora® to oncologists. The central goal of these studies has been to determine whether oncologists treat BTCP themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90 percent of oncologists diagnose and treat BTCP themselves, and do not refer their BTCP patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88 percent of oncologists diagnose and treat BTCP themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition which should be monitored by the treating oncologist.)

194. Despite these overwhelming results from its own market research, Cephalon continues to sell Fentora® through its general pain sales force to general pain specialists, even though it knows that it is missing approximately 90 percent of the on-label patient population.

195. In fact, Cephalon has set sales quotas for its general pain sales force that would be unattainable if they did not promote Fentora® off-label. Thus, the pain sales representatives have, from the outset, been required to adhere to call lists that include numerous pain doctors and

other physicians who would not prescribe Fentora® on-label, and few, if any, oncologists. Evidently, Cephalon has determined that capturing the off-label market will be more lucrative. Indeed, a recent internal forecast showed that peak sales for on-label use of Fentora® would only be about $150 million.

196. Not surprisingly, a 2009 PowerPoint presentation by Cephalon's Associate Director of Oncology for Strategic Analysis & Planning, Kathy Roman, confirms that only 4% of Fentora® prescriptions are written by oncologists (although they are the only physicians likely to prescribe Fentora® on-label), while 44% are written by pain doctors, 20% are written by primary care physicians, 14% are written by nurse practitioners and physician assistants, 6% percent are written by neurologists, and 12% are written by "other" healthcare professionals.

D. THE FRAUDULENT MARKETING SCHEME FOR FENTORA® HAS BEEN A FINANCIAL BONANZA FOR CEPHALON

197. From its launch on October 1, 2006 through the first quarter of 2010, Fentora® has achieved nearly $430 million in sales. U.S. sales of Fentora® are expected to increase to $200 million in 2010 (*i.e.*, 30% more than the projected on-label market), which would reflect an increase of approximately 150% over 2009.

VIII. CEPHALON'S OFF-LABEL PROMOTION VIOLATES THE CORPORATE INTEGRITY AGREEMENT

198. Cephalon's continuing promotion of Treanda® and Fentora® for off-label use is a flagrant violation of its Corporate Integrity Agreement and a stunning admission that the company learned nothing from its prior plea agreement.

199. Cephalon knows the risks inherent in the unlawful marketing and promotion of Treanda® and Fentora®, because its first brush with the law resulted in a September 2008 Settlement Agreement with the Federal Government and various *Qui Tam* States. As part of that settlement, Cephalon was required to enter into a five-year CIA that expressly incorporated measures aimed at prohibiting the company from engaging in any further off-label promotions.

200. The CIA requires Cephalon to notify the Government of any "reportable events," defined to include any "matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized." Cephalon intentionally has ignored that requirement.

201. The CIA requires that Cephalon's Board and top management regularly certify that the company has an effective compliance program and is in compliance with all applicable

requirements. Cephalon intentionally has ignored that requirement (or has filed knowingly false certifications).

202. From the day Cephalon signed the CIA and announced, "[w]e believe our existing compliance policies and procedures already address the majority of the requirements outlined in the CIA and that the strong compliance infrastructure now in place has improved the accountability of our employees and the transparency of our actions", it has known that statement to be false.

203. Rather than comply with the CIA, Cephalon has ignored both its letter and its spirit. From the highest levels of the company, Cephalon has done all it can to subvert the intentions of Federal law, regulations and the CIA in order to maximize corporate profits while still participating in Federal and State healthcare reimbursement programs. Cephalon's unvisited pursuit of profits is all the more contemptible because of the very significant known health risks posed by the drugs at issue.

IX. THE FRAUDULENT MARKETING SCHEMES CAUSED THE SUBMISSION OF MULTIPLE FALSE CLAIMS, RESULTING IN IMPROPER PAYMENTS BY GOVERNMENT PROGRAMS AND THE QUI TAM STATES.

204. Cephalon's Fraudulent Marketing Schemes served their intended purpose, as they induced doctors to write off-label prescriptions for Treanda® and Fentora®, causing them to submit false claims for reimbursement and resulting in hundreds of millions of dollars in improper payments by Government Programs and the *Qui Tam* States.

205. Due in part to Cephalon's illegal conduct, Treanda® and Fentora® have been heavily used for the treatment of Medicaid, Medicare Part B and Part D and other Government Program participants and beneficiaries. Thus, Cephalon's illegal conduct has caused the

Government Programs and *Qui Tam* States to pay hundreds of millions of dollars that they should not have paid, enriching Cephalon.

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1))

206. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

207. Defendants knowingly presented and caused to be presented to the Government false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1).

208. As a result of Defendants' actions as set forth above in this Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2))

209. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

210. Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of a false or fraudulent claims, thereby causing false or fraudulent claims for payment to actually be paid or approved, in violation of 31 U.S.C. § 3729(a)(2).

211. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Treanda® and Fentora® prescribed to patients enrolled in Government Programs.

212. As a result of Defendants' actions as set forth above in this Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3))

213. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

214. As detailed above, Defendants knowingly conspired with the various health care professionals identified and described herein to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

215. As a result of Defendants' actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of California False Claims Act)

216. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

217. This is a civil action brought by Relator on behalf of the State of California against Defendants under the California False Claims Act, CAL. CODE § 12652(c).

218. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of California or its political subdivisions false or fraudulent claims for payment, in violation of CAL. CODE § 12651(a)(1).

219. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to get false or fraudulent claims paid in violation of CAL. CODE § 12651(a)(2).

220. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of CAL. CODE § 1265 1 (a)(7).

221. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

222. As a result of Defendants' actions as set forth above, the State of California, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT V
(Violation of Colorado Medicaid False Claims Act)

223. Relator incorporated herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

224. This is a civil action brought by Relator on behalf of the State of Colorado against Defendants under the State of Colorado False Claims Act, COLO. REV. STAT. § 25.5-4-304.

225. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of COLO. REV. STAT. § 25.5-4-305(a).

226. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of COLO. REV. STAT. § 25.5-4-305(b).

227. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado or one of its political subdivisions, in violation of COLO. REV. STAT. § 25.5-4-305(f).

228. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

229. As a result of Defendants' actions, as set forth above, the State of Colorado or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VI
(Violation of Connecticut False Claims Act)

230. Relator incorporated herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

231. This is a civil action brought by Relator on behalf of the State of Connecticut against Defendants under the Connecticut False Claims Act, 2009 Conn. Pub. Acts No. 09-5.

232. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of 2009 Conn. Pub. Acts No. 09-5 § 2(a)(1).

233. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of Conn. Pub. Acts No. 09-5 § 2(a)(2).

234. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions in violation of Conn. Pub. Acts No. 09-5 § 2(a)(1).

235. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of state and state subdivision funded health insurance programs.

236. As a result of Defendants' actions as set forth above, the State of Connecticut, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT VII
(Violation of Delaware False Claims and Report Act)

237. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

238. This is a civil action brought by Relator on behalf of the Government of the State of Delaware against Defendants under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

239. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, directly or indirectly, to an officer or employee of the Government of the State of Delaware false or fraudulent claims for payment or approval, in violation of DEL. CODE ANN. tit. 6, §1201 (a)(1).

240. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved, in violation of DEL. CODE ANN. tit. 6, §1201(a)(2).

241. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the Government of Delaware, in violation of DEL. CODE ANN. tit. 6, § 1201(a)(7).

242. The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

243. As a result of Defendants' actions, the Government of the State of Delaware has been, and may continue to be, severely damaged.

COUNT VIII
(Violation of District of Columbia False Claims Act)

244. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

245. This is a civil action brought by Relator in the name of the District of Columbia against Defendants under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(a).

246. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an

officer or employee of the District, a false or fraudulent claim for payment or approval, in violation of D.C. CODE ANN. § 2-308.14(a)(l).

247. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records and/or statements to get false claims paid or approved by the District, in violation of D.C. CODE ANN. § 2-308.14(a)(2).

248. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, in violation of D.C. CODE ANN. § 2-308.14(a)(7).

249. The District of Columbia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

250. As a result of Defendants' actions, as set forth above, the District of Columbia has been, and continues to be, severely damaged.

COUNT IX
(Violation of Florida False Claims Act)

251. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

252. This is a civil action brought by Relator on behalf of the State of Florida against Defendants under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

253. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Florida or one of its agencies false or fraudulent claims for payment or approval, in violation of FLA. STAT. ANN. § 68.082(2)(a).

254. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(b).

255. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082 (2)(g).

256. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

257. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT X
(Violation of Georgia Medicaid False Claims Act)

258. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

259. This is a civil action brought by Relator, in the name of the State of Georgia, against Defendants pursuant to the State of Georgia Medicaid Fraud False Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

260. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Georgia Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

261. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of GA. CODE ANN. § 49-4-168 (2007).

262. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or

quantity than is due or when no benefit or payment is authorized, in violation of GA. CODE ANN. § 49-4-168 (2007).

263. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

264. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

265. As a result of Defendants' actions, as set forth above, the State of Georgia or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XI
(Violation of Hawaii False Claims Act)

266. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

267. This is a civil action brought by Relator on behalf of the State of Hawaii and its political subdivisions against Defendants under the State of Hawaii's False Claims Act -False Claims to the State, HAW. REV. STAT. § 661-25.

268. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of HAW. REV. STAT. § 61-21(a)(l).

269. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(2).

270. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(7).

271. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

272. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Illinois Whistleblower Reward and Protection Act)

273. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

274. This is a civil action brought by Relator on behalf of the State of Illinois against Defendants under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL, COMP. STAT. ANN. 175/4(b).

275. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois or a member of the Illinois National Guard a false or fraudulent claim for payment or approval, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(I).

276. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(2).

277. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(7).

278. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

279. As a result of Defendants' actions, as set forth above, the State of Illinois has been, and may continue to be, severely damaged.

COUNT XIII
Violation of Indiana False Claims and Whistleblower Protection Act)

280. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

281. This is a civil action brought by Relator on behalf of the State of Indiana against Defendants under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

282. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(l).

283. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain payment or approval of false claims by the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(2).

284. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(6).

285. The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

286. As a result of Defendants' actions, as set forth above, the State of Indiana has been, and may continue to be, severely damaged.

COUNT XIV
(Violation of Louisiana Medical Assistance Programs Integrity Law)

287. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

288. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs against Defendants under the State of Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. § 46:439.1.

289. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

290. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of LA. REV. STAT. § 46:438.3(B).

291. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of LA. REV. STAT, § 46:438.3 (D).

292. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

293. As a result of Defendants' actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Massachusetts False Claims Act)

294. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

295. This is a civil action brought by Relator on behalf of the Commonwealth of Massachusetts against Defendants under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

296. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MASS. LAWS ANN, ch. 12, § 5B(1).

297. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts or its political subdivisions in violation of MASS. LAWS ANN. ch. 12, § 5B(2).

298. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or one of its political subdivisions, in violation of MASS. LAWS ANN. ch. 12, § 5B(8).

299. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and

prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

300. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Michigan Medicaid False Claims Act)

301. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

302. This is a civil action brought by Relator in the name of the State of Michigan against Defendants under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).

303. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of MICH. COMP. LAWS. SERV. § 400.603(1).

304. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit, in violation of MICH. COMP. LAWS. SERV. § 400.603(2).

305. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants are not entitled or in an amount greater than that to which Defendants are entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

306. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly presented or made or caused to be presented or made, and may still be presenting or causing to be presented a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, in violation of MICH. COMP. LAWS. SERV. § 400.607(1).

307. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

308. As a result of Defendants' actions, as set forth above, the State of Michigan or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Minnesota False Claims Act)

309. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

310. This is a civil action brought by Relator on behalf of the State of Minnesota against Defendants under the State of Minnesota False Claims Act, Minn. Stat. § 15C.01.

311. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

312. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of Minn. Stat. § 15C.02(a)(2).

313. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota or one of its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

314. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

315. As a result of Defendants' actions, as set forth above, the State of Minnesota or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Montana False Claims Act)

316. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

317. This is a civil action brought by Relator on behalf of the State of Montana against Defendants under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

318. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(l)(a).

319. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

320. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana or one of its political subdivisions, in violation of MONT. CODE ANN. § 17-8-403(l)(g).

321. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

322. As a result of Defendants' actions, as set forth above, the State of Montana or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of Nevada Submission of False Claims to State or Local Government Act)

323. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

324. This is a civil action brought by Relator on behalf of the State of Nevada against Defendants under the State of Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. ANN. § 357.080(1)

325. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(l)(a).

326. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

327. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada or one of its political subdivisions, in violation of NEV. REV. STAT. ANN. § 357.040(1)(g).

328. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

329. As a result of Defendants' actions, as set forth above, the State of Nevada or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of New Hampshire Medicaid False Claims Act)

330. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

331. This is a civil action brought by Relator on behalf of the State of New Hampshire against Defendants under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

332. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

333. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a fake claim paid or approved, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(b).

334. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire or one of its political subdivisions, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(e).

335. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

336. As a result of Defendants' actions, the State of New Hampshire or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
(Violation of New Jersey False Claims Act)

337. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

338. This is a civil action brought by Relator, in the name of the State of New Jersey, against Defendants pursuant to the State of New Jersey Fraud False Claims Act, N.J. STAT. ANN. § 265 (2007), *et seq.*

339. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the New Jersey Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

340. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of N.J. STAT. ANN. § 265 (2007).

341. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.J. STAT. ANN. § 265 (2007).

342. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

343. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

344. As a result of Defendants' actions, as set forth above, the State of New Jersey or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXII
(Violation of New Mexico Medicaid False Claims Act)

345. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

346. This is a civil action brought by Relator on behalf of the State of New Mexico against Defendants under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

347. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

348. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may be continuing to present or causing to be presented a claim for payment under the Medicaid program that is not authorized or is not eligible for benefit under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4B.

349. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved, in violation of N.M. STAT. ANN. § 27-14-4C.

350. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico or one of its political subdivisions, in violation of N.M. STAT. ANN. § 27-14-4E.

351. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

352. As a result of Defendants' actions, as set forth above, the State of New Mexico or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of New York False Claims Act)

353. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

354. This is a civil action brought by Relator on behalf of the State of New York against Defendants under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

355. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

356. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

357. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York or one of its political subdivisions, in violation of N.Y.CLS St. Fin. § 189(g).

358. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

359. As a result of Defendants' actions, as set forth above, the State of New York or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of North Carolina False Claims Act)

360. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

361. This is a civil action brought by Relator on behalf of the State of North Carolina against Defendants under the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605.

362. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.C. GEN. STAT. § 1-607(a)(1).

363. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the State of North Carolina or its political subdivisions in violation of N.C. GEN. STAT. § 1-607(a)(2).

364. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina or one of its political subdivisions, in violation of N.C. GEN. STAT. § 1-607(a)(7).

365. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

366. As a result of Defendants' actions, as set forth above, the State of North Carolina or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of Oklahoma Medicaid False Claims Act)

367. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

368. This is a civil action brought by Relator, in the name of the State of Oklahoma, against Defendants pursuant to the State of Oklahoma Medicaid Fraud False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

369. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Oklahoma Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

370. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

371. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

372. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

373. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

374. As a result of Defendants' actions, as set forth above, the State of Oklahoma or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of Rhode Island False Claims Act)

375. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

376. This is a civil action brought by Relator, in the name of the State of Rhode Island, against Defendants pursuant to the State of Rhode Island Fraud False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

377. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Rhode Island Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

378. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

379. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or

quantity than is due or when no benefit or payment is authorized, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

380. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

381. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

382. As a result of Defendants' actions, as set forth above, the State of Rhode Island or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of Tennessee Medicaid False Claims Act)

383. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

384. This is a civil action brought by Relator in the name of the State of Tennessee against Defendants under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

385. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee a claim for payment under the Medicaid program knowing it was false or fraudulent, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(A).

386. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(B).

387. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, relative to the Medicaid program, with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(D).

388. The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

389. As a result of Defendants' actions, as set forth above, the State of Tennessee has been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Texas Human Resources Code, Medicaid Fraud Prevention Chapter)

390. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

391. This is a civil action brought by Relator in the name of the State of Texas against Defendants under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

392. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for a contract, benefit or payment under a Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(1).

393. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact that is intended to be used, and has been used, to determine a person's eligibility for a benefit or payment under the Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(2).

394. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or

state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of TEX. HUM. RES. CODE § 36.002(4)(B).

395. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made a claim under the Medicaid program for a service or product that was inappropriate, in violation of TEX. HUM. RES. CODE § 36.002(7)(C),

396. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

397. As a result of Defendants' actions, as set forth above, the State of Texas, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Virginia Fraud Against Taxpayers Act)

398. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

399. This is a civil action brought by Relator on behalf of the Commonwealth of Virginia against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq.*

400. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an

officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval, in violation of VA. CODE ANN. § 8.01-216.3(A)(l).

401. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(2).

402. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(7).

403. The Commonwealth of Virginia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

404. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Wisconsin False Claims for Medical Assistance Act)

405. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

406. This is a civil action brought by Relator on behalf of the State of Wisconsin against Defendant under the State of Wisconsin False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

407. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the state, a false or fraudulent claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(a) (2007).

408. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(b).

409. The State of Wisconsin, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

410. As a result of Defendant' actions, as set forth above, the State of Wisconsin, its political subdivisions or the Department has been, and may continue to be, severely damaged.

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729, et seq., CAL. CODE § 12650, et seq., COLO. REV. STAT. § 25.5-4-304 et seq., 2009 CONN. PUB. ACTS NO. 09-5, et seq., DEL. CODE

ANN. tit. 6, § 1201, et seq., D.C. CODE ANN. § 2-308.13, et seq., FLA. STAT. ANN. § 68.081, et seq., GA. CODE ANN. § 49-4-168, et seq., HAW. REV. STAT. § 661-21, et seq., 740 ILL. COMP. STAT. ANN. § 1751, et seq., IND. CODE ANN. § 5-11-5.5, et seq., LA. REV. STAT. § 437.1, et seq., MASS. LAWS ANN. Ch. 12, §5A, et seq., MICH. COMP. LAWS SERV. § 400.601, et seq., MINN. STAT. § 15C.01 et seq., MONT. CODE ANN. § 17-8-401, et seq., NEV. REV. STAT. ANN. § 357.010, et seq., N.H. REV. STAT. ANN. § 167:61-b, et seq., N.J. STAT ANN. § 265, et seq., N.M. STAT. ANN. § 27-14-1, et seq., N.Y. CLS ST. FIN. § 187, et seq., N.C. GEN. STAT. § 1-605, et. seq., OKLA. STAT. tit. 63, § 5053, et seq., R.I. GEN. LAWS § 9-1,1-1, et seq., TENN. CODE ANN. § 71-5-181, et seq., TEX. HUM. RES. CODE § 36.001, et seq., VA. CODE ANN. § 8.01-216.1, et seq., and WIS. STAT. § 20.931 (2007), et seq.;

B. That judgment be entered in Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator Doe be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), CAL. CODE § 12652(g), COLO. REV. STAT. § 25.5-4-306(4), 2009 Conn. Pub. Acts No. 09-5 § 5 (e), DEL. CODE ANN. tit. 6, § 1205, D.C. CODE ANN. § 2-308.15(f), FLA. STAT. ANN. § 68.085, GA. CODE ANN. § 49-4-168, HAW. REV. STAT. § 661-27, 740 ILL. COMP. STAT. ANN. 175/4(d), IND. CODE ANN. § 5-11-5.5-6(a), LA. REV. STAT.

§ 439.4, MASS. GEN. LAWS ch. 12, § 5F, MICH. COMP. LAWS SERV. § 400.610a(9), MINN. STAT. § 15C.13, MONT. CODE ANN. § 17-8-410, NEV. REV. STAT. ANN. § 357.220, N.H. REV. STAT. ANN. § 167:61-e, N.J. STAT ANN. § 265, N.M. STAT. ANN. § 27-14-9, N.Y. CLS St. Fin. § 190.6., N.C. GEN. STAT. § 1-607(a), OKLA. STAT. tit. 63, § 5053, R.I. GEN. LAWS § 9-1,1-1, TENN. CODE ANN. § 71-5-183, TEX. HUM. RES. CODE § 36.110, VA. CODE ANN. § 8.01-216.7, and WIS. STAT. § 20.931;

D. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars ($10,000) per claim as provided by CAL. CODE § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the Government of the State of Colorado multiplied as provided for in COLO. REV. STAT. § 25.5-4-305, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Colorado Medicaid False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Colorado for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the Government of the State of Connecticut multiplied as

provided for in 2009 Conn. Pub. Acts No. 09-5 § 2(b), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Pub. Acts No. 09-5 § 2(b), to the extent such multiplied penalties shall fairly compensate the Government of the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the Government of the State of Delaware multiplied as provided for in DEL. CODE ANN. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five- hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Delaware False Claims and Reporting Act, as provided by DEL. CODE ANN. tit. 6, § 1201(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. CODE ANN. § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. CODE ANN. § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in FLA. STAT. ANN. § 68.082, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by FLA. STAT. ANN. § 68.082, to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in GA. CODE ANN. § 49-4-168, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent of the proceeds per claim as provided by GA. CODE ANN. § 49-4-168.2, to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in HAW. REV. STAT. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by HAW. REV. STAT. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 ILL. COMP. STAT, ANN. 175/3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000), and the costs of this civil action brought to recover such damages and penalty, as provided by 740 ILL. COMP. STAT. ANN. 175/3(a), to the extent such multiplied penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in IND. CODE ANN. § 5-11-5.5-2, plus a civil penalty of at least five thousand dollars ($5,000) as provided by IND. CODE ANN. § 5-11-5.5-2, to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in LA. REV. STAT § 438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by LA. REV. STAT § 438.6(B)(I), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by LA. REV. STAT § 438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6

at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by LA. REV. STAT. § 438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, 65B, multiplied as provided for in MASS. LAWS ANN. ch. 12, § 5B, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to MASS. LAWS ANN, ch. 12, 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MICH. COMP. LAWS SERV. §§ 400.603-400.606, 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the Government of the State of Minnesota multiplied as provided for in MINN. STAT. § 15C.02(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Minnesota False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Minnesota for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MONT. CODE ANN. § 17-8-403(2), multiplied as provided for in MONT. CODE ANN. § 17-8-403(2), plus a civil penalty of up to ten thousand dollars ($10,000) for each false claim, pursuant to MONT. CODE ANN. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in NEV. REV. STAT. ANN. 357.040, multiplied as provided for in NEV. REV. STAT. ANN. § 357.040(1), plus a civil penalty of not less than two thousand dollars ($2,000) or more than ten thousand dollars ($10,000) for each act, pursuant to NEV. REV. STAT. ANN. § 357.040, to the extent such

multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of New Hampshire or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:6111, multiplied as provided for in N.H. REV. STAT. ANN. § 167:61II, plus a civil penalty of two thousand dollars ($2,000) for each false claim, pursuant to REV. STAT. ANN. § 167:61II, to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. STAT. ANN. § 265, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by N.J. STAT. ANN. § 265, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for

in N.M. STAT. ANN. § 27-14-4, multiplied as provided for in N.M. STAT. ANN. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after fill discovery;

W. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. CLS St. Fin. § 189.1., multiplied as provided for in N.Y. CLS St. Fin. § 189.1., plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. CLS St. Fin. § 189.l., to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. GEN. STAT. § 1-605, multiplied as provided for in N.C. GEN. STAT. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. GEN. STAT. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in OKLA. STAT. tit. 63, § 5053, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by OKLA. STAT. tit. 63, § 5053.4, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. GEN. LAWS § 9-1,1-1, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by R.I. GEN. LAWS § 9-1,1-4, to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TENN. CODE ANN. § 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) pursuant to TENN. CODE ANN. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by

Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator Doe's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(l), multiplied as provided for in TEX. HUM. RES. CODE § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to TEX. HUM. RES. CODE § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to TEX. HUM. RES. CODE § 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator Doe's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in VA. CODE ANN. § 8.01-216.3(A), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by VA. CODE ANN. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of

Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator Doe's favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in WIS. STAT. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by WIS. STAT. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

EE. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

FF. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

GG. That Relator be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(a), plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: August 30, 2010

BLANK ROME LLP
Attorneys for Plaintiff/Relator Doe

By: _____

Leonard D. Steinman
Jeremy L. Reiss
The Chrysler Building
405 Lexington Avenue
New York, NY 10174
(212) 885-5000

- and-

W. Scott Simmer
Alan F. Freeman
Andrew M. Miller
600 New Hampshire Avenue, NW
Washington, DC 20037