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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* MATTHEW CESTRA, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, the Commonwealth of MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, the Commonwealth of VIRGINIA, WASHINGTON, WISCONSIN and the DISTRICT OF COLUMBIA, *Plaintiffs,* v. CEPHALON, INC., a Wholly-Owned, Direct Subsidiary of TEVA LIMITED, and JOHN DOES # 1-100, FICTITIOUS NAMES, *Defendants.*	10—CIV—6457 (SHS)

CORRECTED SECOND AMENDED COMPLAINT AND JURY DEMAND

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CORRECTED SECOND AMENDED 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 Matthew Cestra, 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.* and pursuant to the following State *qui tam* statutes: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.* (2010); the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301a *et seq.* (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.* (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.* (2000); the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.* (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (2006); the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1 *et seq.* (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (2007); the Iowa False Claims Act, Iowa Code § 685.1 *et seq.* (2010); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.* (2006); the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 *et seq.* (LexisNexis 2010); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.* (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.* (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.* (2007); the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.* (West 2007); the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.* (McKinney 2010); the North Carolina

False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2011); the Washington Medicaid False Claims Act, S. 5978, 62nd Cong. § 201 *et seq.* (2012); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.* (2007) ("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, a pharmaceutical company, has orchestrated and engaged in a scheme to cause the submission of hundreds of thousands of false claims to federal and state health care programs by falsely and misleadingly promoting its drugs Treanda® and Fentora® for off-label, non-medically accepted uses that are ineligible for reimbursement by Government health care programs.

3. Treanda®, a chemotherapy drug, was approved in October 2008 as a second-line treatment for indolent non-Hodgkin's lymphoma in patients whose cancer had progressed after treatment with another chemotherapy regimen. The market for second-line treatment, however, was relatively small compared to the front-line market, where the standard of care was a

combination regimen of five drugs, referred to as R-CHOP, which had been pioneered by M.D. Anderson and demonstrated as effective by substantial clinical evidence.

4. In order to increase sales beyond the modest potential of the second-line market, Cephalon sought to displace R-CHOP as the front-line standard of care with a two-drug regimen containing Treanda® and rituximab, despite the lack of reliable clinical evidence demonstrating the effectiveness of Treanda® plus rituximab compared to R-CHOP in the front-line setting. The burden of proof for displacing a front-line standard of care is high, in order to avoid depriving patients of a treatment that has been clearly established as effective and safe in favor of one whose benefits have not been clearly demonstrated; however, the only evidence of Treanda®'s front-line effectiveness was a single, significantly flawed trial conducted by a German cooperative group (the "Rummel study"), which possessed serious deficiencies in its design, monitoring, and record-keeping. Not only was the study refused by the FDA as an adequate basis to approve Treanda® for front-line use (despite Cephalon's considerable efforts), it was not published by a peer-reviewed journal until April 2013, over four years after Cephalon began its promotion of Treanda® in the front-line setting.

5. Internally, Cephalon's senior executives acknowledged that the Rummel study's flaws were so significant that they expected the results from the BRIGHT study, another ongoing clinical trial of front-line use, would likely contradict the Rummel study's results and show Treanda® to be less effective for front-line use than R-CHOP. The slow progression of iNHL and corresponding length of time required to conduct clinical trials in iNHL, however, meant that the final results for BRIGHT's key endpoints (progression free survival and overall survival) would not become available until after the patent expiration for Treanda®. The adverse impact

on Cephalon's profits if BRIGHT contradicted Rummel, Cephalon's executives concluded, would therefore be minimal.

6. While internally expressing disbelief in the reliability of the Rummel study's results, externally Cephalon promoted the Rummel study as definitive evidence of the superiority of the Treanda®-based regimen for front-line use. Cephalon trained its sales representatives to promote the Rummel study as evidence of Treanda®'s superiority for front-line use, and it used Advisory Board meetings, promotional speaker programs, and faux market research surveys to disseminate that same message. Cephalon also illegally influenced the content of continuing medical education events, which it leveraged as vehicles to promote Treanda® for front-line use. Through Advisory Boards and promotional speaker programs, Cephalon also paid physicians kickbacks to induce their front-line prescribing of Treanda®.

7. Cephalon's regulatory, medical affairs, and marketing teams deliberately misled oncologists into believing that the Rummel study constituted reliable evidence of Treanda®'s superiority to R-CHOP for front-line treatment of iNHL by not disclosing to oncologists or the broader public what Cephalon knew to be the study's significant flaws. In its attempt to create a new standard of care for the treatment of iNHL, Cephalon has held up the Rummel study as a clinical breakthrough, allowing the Company to stave off the FDA and the Government while reaping hundreds of millions of dollars in profits from the off-label sales of Treanda®.

8. Cephalon engaged in similar fraudulent promotion to expand the use of its potent opioid Fentora® from its limited approved patient population of treating cancer patients with breakthrough pain, to the treatment of *all* pain patients. Fentora® is a rapid-release opioid analgesic, approved to treat breakthrough cancer pain—pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain—in cancer

patients who are already receiving and tolerant of around-the-clock opioid therapy to treat their underlying cancer pain.

9. Because of its potency and rapid-onset, even relative to other opioids, Fentora® is particularly dangerous and susceptible to abuse and misuse, and its FDA-approved Prescribing Information includes a black box warning emphasizing the danger of abuse. Fentora®'s potency is so great—some 100 times greater than morphine—that non-opioid-tolerant patients who take Fentora® risk death. Largely in recognition of Fentora®'s unique dangers, the FDA followed the recommendation of its Advisory Committee and explicitly refused to approve Fentora® for the treatment of non-cancer breakthrough pain.

10. Despite the FDA's refusal to approve Fentora® for use in non-cancer patients, Cephalon long promoted and, following the denial of its sNDA, continued to promote Fentora® for treatment of various forms of pain in non-cancer patients, which was a far more profitable market than that of Fentora®'s on-label indication. In fact, Fentora®'s entire marketing strategy centered on off-label promotion to non-cancer patients. Despite the results of its own market research study showing that on-label breakthrough cancer pain is treated by oncologists, for a considerable period Cephalon did not promote Fentora® to oncologists at all, but only to pain specialists who did not treat cancer patients. For example, Cephalon targeted sports medicine physicians for the treatment of low back pain. Cephalon's off-label promotion was inherently misleading because Fentora® was not safe for the off-label uses for which Cephalon promoted it, even though Cephalon's sales representatives claimed that it was.

11. Cephalon's off-label promotion of Fentora® is particularly egregious, given that it recently paid a substantial amount to settle allegations that it promoted Actiq®, a predecessor drug to Fentora® with the same active ingredient and FDA-approved indication, in precisely the

same manner it is now promoting Fentora®. In September 2008 the Company entered into an agreement with the U.S. Department of Justice in which it paid $425 million to settle civil and criminal charges that included its illegal off-label promotion of Actiq® for patients with non-cancer pain. The Company subsequently signed a CIA with the OIG, agreeing to implement a rigorous, five-year compliance program that would eliminate misbranding and prevent illegal kickbacks from being paid to induce prescribing of its products.

12. However, while Cephalon has represented to the Government that it is a changed company, the only true change in Cephalon's illegal conduct has been the increased diligence with which Cephalon attempts to conceal that conduct. Indeed, a key component of Cephalon's fraudulent marketing scheme was to convert physicians who prescribed Actiq® for off-label uses to prescribe Fentora® for those same off-label uses. In order to conceal its ongoing fraudulent activity from the Government, Cephalon intentionally provided false and misleading information in the quarterly reports it was required to submit to the OIG, and concealed altogether conduct the Company knew was illegal. Cephalon submitted a false claim each time it submitted a report containing knowingly false information.

13. Not only did Cephalon know that its misleading, off-label promotion would cause physicians to write prescriptions for Treanda® and Fentora® (which would then cause clinics and pharmacies to submit false claims for payment to Government Programs), it was the very purpose of Cephalon's fraudulent scheme that physicians, clinics, and pharmacies would do so, and that Cephalon would profit as a result. Cephalon's fraudulent scheme was hugely successful, and payments of false claims for Treanda® and Fentora® by Government Programs have been substantial. Cephalon has profited handsomely, and the fraudulent scheme is ongoing.

14. Cephalon's off-label promotion of Treanda® and 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 Treanda®. These false statements regarding Treanda® and Fentora® included the quarterly reports filed with the OIG as part of Cephalon's obligations under the CIA. Had the Federal and *Qui Tam* State Governments known that the claims were for off-label uses ineligible for reimbursement, they would not have paid those claims.

II. JURISDICTION AND VENUE

15. 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.

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

17. 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.

18. 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 Matthew Cestra

19. Plaintiff/Relator Matthew Cestra ("Relator Cestra") is a resident of Pittsburgh, Pennsylvania. Relator Cestra originally filed the Second Amended Complaint with the John Doe pseudonym to delay, and perhaps prevent, the very real possibility of employment retaliation. Relator Cestra was formerly employed by Defendant Cephalon as a senior level manager. His responsibilities 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.

20. Relator Cestra is an original source of the allegations in this Corrected Second Amended 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 Corrected Second Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2), including tens of thousands of pages of documents and numerous tape-recorded meetings of high ranking employees. Also prior to filing this Corrected Second Amended Complaint, Relator Cestra brought the wrongdoing described herein to the attention of Cephalon. Relator Cestra has direct and independent knowledge of the allegations and transactions herein.

B. Defendant Cephalon, Inc.

21. Cephalon, Inc. ("Cephalon" or "Company"), 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. Cephalon is a wholly-owned, indirect subsidiary of Teva Limited, which acquired Cephalon in late 2011.

22. Teva Limited is a global pharmaceutical company organized under the laws of Israel with its principal place of business in Israel.

23. 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.

24. Cephalon has a history of illegal off-label promotion and causing the submission of false claims to Government health care programs. In September 2008, the Company entered into a $425 million settlement of criminal and civil allegations regarding illegal promotion of Actiq®, Provigil®, and Gabitril®, which were the only drugs it was then marketing. As part of that settlement, Cephalon entered into a five-year CIA with the 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 instances of off-label promotion and kickbacks; and (iii) self-report instances of off-label promotion and kickbacks.

25. At the time of the settlement and criminal plea, Valli Baldassano, Cephalon's chief compliance officer, stated that "[c]ompliance infrastructure now in place has improved the accountability of our employees and the transparency of our actions." However, Cephalon's off-label promotion and payment of kickbacks to induce prescribing of its products has continued unabated.

26. Notwithstanding its having entered into the CIA, as alleged herein, Cephalon has promoted by Treanda® and Fentora® off-label and paid kickbacks to induce their prescribing with the intention to cause the submission and payment of false claims 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").

IV. BACKGROUND OF THE REGULATORY FRAMEWORK

A. 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. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

29. 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. 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. 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. 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. 37 Fed. Reg. 16,503 (1972).

30. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. 21 C.F.R. § 314.26.

31. The FDA has set forth general principles for the conduct and performance of clinical trials. These principles have been adopted not only by the agency, but also by the International Conference on Harmonisation, which includes the world's leading medicine control agencies. *See* International Conference on Harmonisation: Guidance on General Considerations for Clinical Trials, 62 Fed. Reg. 66113 (Dec. 17, 1997).

32. Those principles include the following standards for the conduct of clinical trials to support an agency decision that a drug is safe and effective for its intended conditions for use:

(i) The need for trials to be controlled: "Trials should have an adequate control group. Comparisons may be made with placebo, no treatment,

active controls, or of different doses of the drug under investigation. The choice of the comparator depends on, among other things, the objective of the trial. . . . . Historical (external) controls can be justified in some cases, but particular care is important to minimize the likelihood of erroneous inference."

(ii) The need for trials to be randomized: "In conducting a controlled trial, randomized allocation is the preferred means of assuring comparability of test groups and minimizing the possibility of selection bias."

(iii) The need for trials to be blinded: "Blinding is an important means of reducing or minimizing the risk of biased study outcomes. A trial where the treatment assignment is not known by the study participant because of the use of placebo or other methods of masking the intervention is referred to as a single blind study. When the investigator and sponsor staff who are involved in the treatment or clinical evaluation of the subjects and analysis of data are also unaware of the treatment assignments, the study is double blind."

(iv) The need for objective and prospectively determined trial endpoints: A drug's effectiveness is determined if the drug has an effect on an "endpoint." That endpoint can be a clinical benefit, such as survival or a reduction of pain as measured on a validated pain scale; a clinical measurement, such as blood pressure; and, in some cases, a laboratory measurement, such as the amount of virus in the blood stream. All endpoints need to reflect clinical benefit. An endpoint that indirectly

reflects a clinical benefit, such as a laboratory measurement, is known as a "surrogate endpoint." Endpoints should be defined prospectively (i.e., before the trial begins), giving descriptions of methods of observation and quantification. Objective methods of observation should be used where possible and when appropriate. A primary endpoint should reflect clinically relevant effects and is typically selected based on the principal objective of the study. Secondary endpoints assess other drug effects that may or may not be related to the primary endpoint. Endpoints and the plan for their analysis should be prospectively specified in the protocol. The method used to make the measurements of the endpoints, both subjective and objective, should be validated and meet appropriate standards for accuracy, precision, reproducibility, reliability and responsiveness (sensitivity to change over time).

33. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998. *See, e.g.* Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979); *Warner-Lambert Co. v. Hecker*, 787 F.2d 147 (3d

Cir. 1986). FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different endpoints, to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

34. In other cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval – generally only in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been

substantial progress in the science of drug development resulting in higher quality clinical trial data.

35. Cases where the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multicenter trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

36. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

B. The FDA May Refuse to File a Sponsor's New Drug Application ("NDA")

37. Within sixty days of receiving an NDA (including an sNDA for an additional indication for a drug already approved for a different use) the FDA will make a determination as to whether that application may be filed. 21 C.F.R. § 314.101(a)(l). "The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review." Id.

38. Reasons that an application may fail this threshold determination are enumerated in subsections (d) and (e). As outlined in the FDA's 1993 guidance on the topic, one frequent reason for refusing to file an application is "[c]lear failure to include evidence of effectiveness

compatible with the statute and regulations," including "lack of any adequate and well-controlled studies," as defined by 21 C.F.R. § 314.126, or "use of a study design clearly inappropriate (as reflected in regulations or well-established agency interpretation)." *See* FDA, *New Drug Evaluation Guidance Document: Refusal to File*, 4-5 (July 12, 1993), *available at*, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformationiGuidancesIUCM080561.pdf.

39. The refuse-to-file decision is made by one of the FDA's New Drug Review Divisions. If the relevant Division determines that an application fails to meet the requisite threshold, it prepares a letter advising the applicant of the decision and listing the reasons for that decision. *Id.* at 7. The FDA does not publicly disclose these refuse-to-file letters.

40. While in the past only the most "extreme deficiencies" have resulted in a refusal to file, the provision has more recently been applied to applications containing "less extreme deficiencies" that are nonetheless "severe enough to make the application not approvable without major modification." *Id.* at 1. Recent news articles confirm the perception that the FDA has started to issue an increased number of refuse-to-file letters. *See, e.g.*, *Analysis: Refuse-to-File Letters Mount, Suggests Policy Change*, 43 Washington Drug Letter 18 (May 2, 2011).

41. Despite this increased use of refusal-to-file letters, however, the guidance makes clear that refusals should still be "reserved for applications with defects that make the application plainly inadequate, non-reviewable without major repair, or that make review unreasonably difficult." Guidance Document at 3. "The [refusal to file] is not an appropriate vehicle for dealing with complex and close judgments on such matters as balancing risks and benefits, magnitude of drug effect, acceptability of a plausible surrogate market, or nuances of study design." *Id.* Debate of these complex issues is appropriately reserved for a substantive review.

As such, refusals to file remain rare: since 1998, companies have disclosed only twenty-eight such refusals (although the fact that the FDA does not itself publicly disclose refusals means that the agency may have issued more). *See Analysis: Refuse-to-File Letters Mount, supra.*

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

42. 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.

43. 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.

44. 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."

45. "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.

46. 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.

47. 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).

48. 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).

49. 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.

50. 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. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs are not based on misleading marketing tactics.

V. PRESCRIPTION DRUG PAYMENT UNDER GOVERNMENT PROGRAMS

51. Whether a drug is FDA approved for a particular indication (i.e., use) and whether that indication is recommended in one or more of the statutorily named drug Compendia

determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

A. The Medicaid Program

1. Medicaid Only Reimburses Drugs Used for Medically Accepted Indications

52. 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 and state governments. Prior to the advent of Medicare Part D in 2006, the Medicaid program subsidized the purchase of more prescription drugs than any other program in the United States.

53. 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." 42 U.S.C. § 1396r-8(k)(3).

54. 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. 42 U.S.C. § 1396r-8(k)(6). The three statutorily named Compendia are the American Hospital Service Formulary Drug Information ("AHFS"), United States Pharmacopeia-Drug Information or its successor publications ("USP-DI"), and the DRUGDEX Information System ("Drugdex"). 42 U.S.C. § 1396r-8(g)(1)(B)(i). The USP-DI ceased publication in 2007 and has no successor publications recognized by CMS.

55. 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, Cephalon corrupted that influence to its own economic advantage.

56. During the time period relevant to this Corrected Second Amended Complaint, Cephalon caused the submission of claims for off-label uses of Treanda® and Fentora® that were ineligible for Medicaid reimbursement because the uses were neither FDA-approved nor supported by any of the statutorily named Compendia.

2. Off-Label Front-Line Use of Treanda® Was Ineligible for Medicaid Reimbursement

57. From the launch of Treanda® until at least May 25, 2013, none of the statutorily named Compendia supported the use of Treanda® in combination with Rituxan® (or Treanda® as monotherapy) for the front-line treatment of iNHL. AHFS, discussing the Rummel study, described the evidence supporting front-line use as "not fully established." Drugdex contained no recommendation concerning use of Treanda® in combination with Rituxan® (or Treanda® as monotherapy) for front-line treatment of iNHL, and USP-DI ceased publication prior to Treanda®'s launch.

58. From the approval of Treanda® until at least May 25, 2013, the use of Treanda® in combination with Rituxan® for front-line treatment of iNHL was therefore not a medically accepted indication under the Medicaid program, and Treanda® was therefore ineligible for reimbursement for that use. Any claims submitted to Medicaid for payment of Treanda® used to treat front-line iNHL in combination with Rituxan® were therefore false as a matter of law.

3. Fentora® Used to Treat Off-Label Non-Cancer Pain Was Ineligible for Medicaid Reimbursement

59. From the approval of Fentora® until at least May 25, 2013, none of the statutorily named Compendia supported the use of Fentora® for treatment of pain in non-cancer patients. AHFS describes Fentora® as contraindicated for treatment of non-cancer acute and postoperative pain, and Drugdex® contains no citation supporting the use of Fentora® in non-cancer patients. USP-DI contains no recommendation regarding off-label use of Fentora® (although it describes Actiq®, to which Fentora® is a follow-on drug, as contraindicated for treatment of acute and postoperative pain in non-cancer patients).

60. From the approval of Fentora® until at least May 25, 2013, the use of Fentora® to treat breakthrough and other types of pain in non-cancer patients was therefore not a medically accepted indication under the Medicaid program, and Fentora® was therefore ineligible for reimbursement for that use. Any claims submitted to Medicaid for payment of Fentora® used to treat pain in non-cancer patients were therefore false as a matter of law.

B. The Medicare Program

1. Medicare Only Reimburses Drugs Used for Medically Accepted Indications

61. Medicare is a public health care program that provides coverage for Americans over the age of 65, as well as other persons with certain disabilities and diseases. The program is administered by third party contractors known as "carriers," which have some discretion to make coverage determinations, but must so within statutory and regulatory confines.

62. Chemotherapy drugs provided on an outpatient basis, including Treanda®, are covered by Medicare Part B, which provides reimbursement for drugs used in an anticancer chemotherapeutic regimen for a medically accepted indication. 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.

63. For an off-label use of a drug to be medically accepted and hence covered by Medicare Part B, that use must be supported by one of the statutorily named Compendia or other Compendia identified by the Secretary for HHS. 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). In addition, to be covered, the use must also not be "identified as not indicated in one or more such compendia," meaning that an adverse recommendation in one compendium trumps a positive recommendation in another. *Id.* The Medicare Benefit Policy Manual, Ch. 15, Sec. 50.4.5, clarifies that a use is "unsupported" and "not medically accepted by a compendium if the: 1. indication is Category 3 in NCCN or a Class III in Drugdex; or, 2. narrative text in AHFS or Clinical Pharmacology is 'not supportive.'"

64. Until 2008, the only applicable Compendia were those named in the statute: AHFS, USP-DI, and the American Medical Associations Drug Evaluations, the last two of which are defunct. *See* Medicare Benefit Policy Manual, Ch. 15, Sec. 50.4.5. In 2008, under the authority of 42 U.S.C. § 1395x(t)(2)(B)(ii)(I), the Secretary for HHS added three Compendia to the list of applicable Compendia: Drugdex, the National Comprehensive Cancer Network Drugs and Biologics Compendium ("NCCN"), and Clinical Pharmacology.

65. Carriers may also make an exception to these Compendial requirements and provide coverage for a use that does not qualify thereunder if "such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in

publications which have been identified for purposes of this subclause by the Secretary." 42 U.S.C. § 1395x(t)(2)(B)(ii)(II).

66. Pharmacy-dispensed outpatient drugs such as Fentora® are covered by Medicare Part D, which also requires that a "covered Part D drug" be used for a "medically accepted indication (as defined in paragraph (4)." 42 U.S.C.A. § 1395w–102(e)(1). Paragraph 4 in turn refers to the Medicaid definition of medically accepted indication under 42 U.S.C. § 1396r8 (k)(6), which specifies that medically accepted off-label uses are those "supported by one or more citations included or approved for inclusion in any of the Compendia described in AHFS, Drugdex, or USP-DI. Thus, in order to be reimbursable by Medicare Part D, the off-label use of a non-chemotherapeutic drug must be supported by one or more of AHFS, Drugdex, or USP-DI.

67. During the time period relevant to this Corrected Second Amended Complaint, Cephalon caused the submission of claims for off-label uses of Treanda® and Fentora® that were ineligible for Medicare reimbursement because the uses were neither FDA-approved nor supported by the applicable Compendia.

2. Off-Label Front-Line Use of Treanda® Was Ineligible for Medicare Reimbursement

68. From the launch of Treanda® until the publication of the Rummel study on February 20, 2013, Treanda® was ineligible for reimbursement under Medicare for front-line treatment of iNHL in combination with Rituxan® because that use was listed as "not fully established" by AHFS. Pursuant to 42 U.S.C. § 1395x(t)(2)(B)(ii)(I) and sec. 50.4.5 of the Medicare Benefit Policy Manual, the AHFS' adverse recommendation overrode NCCN and Clinical Pharmacology's positive recommendations, and as such, front-line use of Treanda® was ineligible for reimbursement under Medicare Part B. Medicare Carriers were not permitted to make independent determinations to cover Treanda® for front-line use in iNHL because there

was no published, peer-reviewed evidence of Treanda®'s effectiveness for this use until the Rummel study was published on February 20, 2013.

69. From the approval of Treanda® until at least February 20, 2013, the use of Treanda® in combination with Rituxan® for front-line treatment of iNHL was therefore not a medically accepted indication under the Medicare program, and Treanda® was therefore ineligible for reimbursement for that use. Any claims submitted to Medicare for payment of Treanda® used to treat front-line iNHL in combination with Rituxan® were therefore false as a matter of law.

3. Fentora® Used to Treat Off-Label Non-Cancer Pain Was Ineligible for Medicare Reimbursement

70. From the approval of Fentora® until at least May 25, 2013, none of the statutorily named Compendia supported the use of Fentora® for treatment of pain in non-cancer patients. AHFS describes Fentora® as contraindicated for treatment of non-cancer acute and postoperative pain, and Drugdex® contains no citation supporting the use of Fentora® in non-cancer patients. USP-DI contains no recommendation regarding off-label use of Fentora® (although it describes Actiq®, to which Fentora® is a follow-on drug, as contraindicated for treatment of acute and postoperative pain in non-cancer patients).

71. From the approval of Fentora® until at least May 25, 2013, the use of Fentora® to treat breakthrough and other types of pain in non-cancer patients was therefore not a medically accepted indication under the Medicare program, and Fentora® was therefore ineligible for reimbursement for that use. Any claims submitted to Medicare for payment of Fentora® used to treat pain in non-cancer patients were therefore false as a matter of law.

C. Reimbursement Under Other Government Programs

72. 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:

- CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces;
- CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100-percent service-connected disabilities; and
- The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and is administered by the Office of Personnel Management.

73. 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).

74. During the time period relevant to this Corrected Second Amended Complaint, claims submitted to the preceding Government health care programs for the use of Treanda® to treat front-line iNHL and Fentora® to treat pain in non-cancer patients were ineligible for reimbursement and therefore false as a matter of law.

VI. TREANDA®: CEPHALON'S FRAUDULENT MARKETING CAUSED THE SUBMISSION OF FALSE CLAIMS FOR OFF-LABEL USE

A. Background Regarding Treanda® and iNHL

1. *Indolent Non-Hodgkin's Lymphoma (iNHL)*

75. Non-Hodgkin's lymphoma ("NHL") includes a group of cancers affecting the lymphatic system, most often starting in a single lymph node and then spreading to other lymphatic organs such as the spleen and tonsils. NHL may 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. R-CHOP: The Standard of Care for Front-Line Treatment of iNHL

76. The standard of care for the front-line treatment of iNHL is a combination of cyclophosphamide, doxorubicin, vincristine, and prednisolone, plus rituximab, which are collectively referred to as R-CHOP. The use of R-CHOP as a front-line treatment for iNHL was pioneered by M.D. Anderson in Houston, Texas, one of the world's premier cancer centers, and its effectiveness has been clearly established in multiple well-controlled clinical trials.

3. Treanda® (bendamustine)

77. Bendamustine, a derivative of mustard gas, was developed in East Germany in the 1960s, but it was only after fall of the Berlin Wall that bendamustine was introduced in the West.

The chemotherapy is apurine analog-alkylator hybrid, which induces single- and double-strand DNA damage, resulting in programmed cell death.

78. In 2005, Cephalon acquired Treanda®, then still in Phase II testing, from Salmedix, Inc. for $160 million. On March 20, 2008, the FDA approved Treanda® (bendamustine HCl) for the treatment chronic lymphocytic leukemia ("CLL") under the auspices of the Orphan Drug Act, which provides financial incentives for drug companies to develop 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).

79. On October 31, 2008, the FDA approved Treanda® for the treatment of indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The FDA also granted Treanda® orphan drug designation for this indication.

80. Importantly, the market exclusivity provided by orphan drug status is shorter than that provided by typical patents, and as such, Treanda®'s market exclusivity will expire in 2015. This relatively short window of market exclusivity created pressure to maximize sales as quickly as possible, and was largely responsible for driving Cephalon to promote Treanda® for front-line use without obtaining FDA approval or even waiting for reliable evidence of its effectiveness for this use.

81. The market for front-line treatment of iNHL was far larger than Treanda®'s on-label market of second- and third-line use, and Cephalon coveted this much more lucrative front-line market.

4. The Rummel Study

82. In September 2003, Dr. Mathias Rummel of the University Hospital in Giessen, Germany, initiated a cooperative study through the German Study Group for Indolent Lymphomas (the "StiL Group") to compare a combination of bendamustine (Treanda®) plus rituximab ("B-R") against R-CHOP for the front-line treatment of patients with advanced follicular, indolent, and mantle cell lymphomas (the "Rummel study"). At the time, R-CHOP was—and it remains—the standard of care for front-line treatment of iNHL.

83. The study included 549 patients, who were randomized approximately equally between B-R and R-CHOP. Of these, 514 were evaluable in the final analysis. Follicular lymphoma patients accounted for 54% of the sample; mantle cell, 18%; and marginal zone, 13%. In 2007 and 2008, Dr. Rummel made two presentations at annual meetings for the American Society of Hematology ("ASH") of interim results from the study, which showed that B-R was non-inferior to R-CHOP with regard to progression-free survival ("PFS") and possessed a favorable safety profile. On December 5, 2009, at ASH 2009, Dr. Rummel presented the study's final results that B-R was superior to R-CHOP and possessed a favorable safety profile.

84. The Rummel study, however, was designed as a cooperative group study, not as a registration trial and flaws in its methodology and actual conduct undermined the reliability of its results to such an extent that Cephalon's executives believed that its results would likely be contradicted by subsequent clinical trials. Internally, senior management at Cephalon admitted there were significant limitations to the Rummel Study, including:

- The Progression Free Survival ("PFS") endpoint would be difficult to substantiate given study's open-label design, which was susceptible to bias;

- Poor retention of patient scans would make it impossible to independently verify the result;
- Different evaluation schedules between treatment groups potentially introduced time-point bias, where one treatment group was systematically evaluated earlier than, and disease progression recorded earlier than, the other;
- Frequent failures in patient follow-up, which risks selection bias, where patients on one treatment regimen are more diligently followed than those on the other;
- Failure to record adverse events;
- Inadequate site monitoring; and
- Missing narrative descriptions.

85. Thus, it was clear to Cephalon's management that the Rummel study could not serve as the basis for an sNDA for the use of Treanda® as front-line treatment of iNHL.

86. In fact, at a meeting with representatives of Cephalon's Clinical Development and Regulatory departments on August 25, 2010, the FDA expressed numerous concerns regarding the Rummel study and expressed considerable doubt that it could serve as the basis for a front-line sNDA. The FDA spent half of the hour-long meeting discussing its displeasure that Cephalon sought to submit cooperative group data and that the FDA had not been consulted regarding the study's protocol. The FDA also sharply criticized the Rummel study's lack of pharmacokinetic data analyzing the Treanda®-Rituxan® combination, which raised safety concerns about the dosing regimen and the body's long-term exposure to this drug combination. The clear conclusion of the meeting was that the Rummel study alone was an insufficient basis upon which to secure FDA approval for the front-line indication.

87. Nonetheless, despite both the FDA's and its own lack of confidence in the Rummel study's results, Cephalon made it the centerpiece of its fraudulent scheme to promote Treanda® for front-line treatment of iNHL and displace R-CHOP as the standard of care. Since at least September 2008, Cephalon has relied on the Rummel study as the basis for a multi-faceted, off-label campaign to promote Treanda® for the front-line treatment of iNHL. Through the manipulation of CMEs, promotional speaker programs, advisory boards and In-Practice Programs with GPOs, Cephalon has flooded the medical community with glowing portrayals of the flawed study, thereby falsely portraying it as sufficient to support a new standard of care for the front-line treatment of iNHL. The Company's conduct was particularly egregious in that it not only subjected patients to a treatment whose efficacy was not clearly demonstrated, but deprived them of the treatment whose efficacy had been so demonstrated.

5. The BRIGHT Study

88. As part of its promotion of Treanda® for front-line use based on the Rummel study, Cephalon purported to have sufficient confidence in the Rummel study's quality that the study could serve as the basis for the FDA approval of Treanda® for front-line use, although the Company acknowledged internally that the study's quality was too poor for it to actually do so. Nonetheless, to create a façade of pursuit of an FDA indication for front-line use, in April 2009 Cephalon initiated the "BRIGHT study" through the Eastern Cooperative Oncology Group ("ECOG") to compare B-R with R-CHOP as well as another Rituxan®-based regimen, R-CVP. *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) – Referred to as the BRIGHT Study,*

ClinicalTrials.gov Identifier: NCT00877006, *available at*, www.clinicaltrials.gov (last visited May 25, 2013).

89. The BRIGHT study's design, however, was inadequate to provide a basis for a front-line sNDA for Treanda®. As its primary outcome measure, BRIGHT relies on complete response ("CR") rate, which in a slow-progressing disease such as iNHL does not provide reliable evidence of effectiveness. While CR measures the portion of patients who have an initial response to treatment, the critical measure of effectiveness is how long that response is sustained (i.e., progression-free survival ("PFS")), or how long patients live (i.e., overall survival ("OS")). Cephalon knew that the FDA would not approve Treanda® based on a CR endpoint, and indeed, when Cephalon finally submitted an sNDA for front-line use in December 2011, the FDA responded that it required additional data—namely, PFS data from BRIGHT.

90. While the PFS endpoint is the one Cephalon needs to obtain FDA approval, it is also the one that poses the greatest risk of contradicting the Rummel study's positive result. That risk, however, is mitigated for Cephalon by the delay in availability of PFS data until after the expiration of Treanda®'s marketing exclusivity, meaning even a negative result in BRIGHT won't substantively impact Treanda®'s sales.

91. Even though BRIGHT is insufficient to serve as the basis for an FDA indication and will not provide meaningful data until the expiration of Treanda®'s patent, Cephalon conceived of the study as a "veil" that will preserve an illusion of its confidence in the Rummel study, and in doing so not only bolster oncologists' own confidence in the Rummel study and willingness to prescribe Treanda® for front-line iNHL, but deflect Government scrutiny of the Company's illegal off-label promotion of Treanda® based on the Rummel study.

B. Cephalon Executives Doubted the Rummel Study's Result That Treanda® Was as Effective as R-CHOP

92. Cephalon has known that there are serious deficiencies with the Rummel Study—from the methods of data collection to the interpretation and reporting of that data. Yet the Company has taken steps to intentionally conceal the deeply flawed science from both the medical community and Government oversight. While publicly holding out the Rummel study as a ground-breaking transformation in the treatment of iNHL, in private meetings, the Company's senior management has acknowledged that the Rummel study's flaws are too great for even Cephalon's own management to have confidence in the veracity of its results.

93. On Tuesday, February 22, 2011, Cephalon held a Long-Range Planning meeting (which Relator Cestra attended) to discuss a draft PowerPoint slide presentation that Bill Campbell, Vice President for Oncology and Pain Franchises, would be making to Cephalon's Executive Committee. The slide deck contained general information regarding the Company's goals and action plans with respect to its oncology products. Besides VP Campbell (who led the meeting), in attendance were, among others, Matt Shaulis, the newly appointed National Sales Director for Oncology (previously the Senior Director of Marketing); Carol Marchione, the Senior Director of Regulatory Affairs; Jeffrey Wilkins, Cephalon's Vice President of Clinical Research; and Relator Cestra.

94. On the slide that projected future opportunities and risks for Treanda®, Campbell stopped and questioned how the Company would reconcile its publicly stated position (i.e., that it planned to secure FDA approval for the front-line treatment of iNHL) with the reality that both the Rummel and the BRIGHT studies were deeply flawed and would not produce results of sufficient quality to submit to the FDA for approval.

95. Campbell then alerted the attendees to his view that they could not put the true weakness of the Rummel and BRIGHT Studies on the slide because "you cannot say that in public." Per Campbell, if the Company is ever challenged for having promoted Treanda® off-label, "optically" it will need cover with having conducted the BRIGHT study, which ostensibly supports the view that Cephalon believed the Rummel study was of sufficient quality to support an application for a front-line indication.

96. At this point, Senior Director Marchione laughed and told the other senior management that they could tell anyone who would challenge the off-label promotion of Treanda® that no one at the Company had known about the problems with Rummel and BRIGHT, as that had been the Company's official position.

97. Several of Cephalon's senior managers then commented on the poor quality of both studies, noting that Cephalon's own BRIGHT Study would have been shut down long ago, but for the fact that its existence provided cover for Cephalon's off-label promotional activities. Specifically, VP Wilkins told the others in attendance at the meeting that the BRIGHT study gave Cephalon a "Pope-like" "veil" of compliance, providing the Company cover while it promoted Treanda® off-label for the front-line treatment of iNHL.

98. Campbell asked the group whether there was a risk that the BRIGHT study might produce results that contradicted the findings in the Rummel study. Wilkins responded that there was definitely such a risk. Senior Director Marchione added that the final results in Rummel study might actually "go the other way too" after an internal review committee completed its analysis. Wilkins agreed, highlighting that Cephalon's senior management lacked confidence in the clinical merit of the Rummel study and doubted its result that Treanda®-Rituxan® was equivalent to R-CHOP for treatment of front-line iNHL.

99. Marchione then stated that, after spending the time, money and effort to conduct an audit of the Rummel study data, Cephalon's Regulatory Department had confirmed that the data was insufficient to support the Company's claims, much less obtain FDA approval for front-line treatment. According to Marchione and Wilkins, after Cephalon had analyzed the Rummel data, it had concluded that the results would be considerably less efficacious than Rummel himself had previously announced.

100. In addition to the serious flaws she pointed out with the Rummel study, Marchione told everyone in attendance that BRIGHT, too, had serious flaws, including the complete response endpoint and an *ex post facto* design amendment to enroll additional patients to correct the non-inferiority margin. In fact, she relayed that BRIGHT was so bad that the prior head of Cephalon's Oncology Department, Liz Barrett, had sought to shut the study down.

101. For Campbell, however, the main concern remained not developing sound clinical studies to support an iNHL front-line indication, but "optics"—i.e., how Cephalon would respond to any challenge that the Company had promoted Treanda® off-label for the front-line treatment of iNHL when the Company knew there was no reliable clinical support for this claim.

102. At this point, VP Campbell again asked those in attendance what message should be put on the slide for the Executive Committee about Treanda®'s immediate prospects in the front-line setting. Campbell acknowledged the consensus was that the Rummel and BRIGHT studies represented "high risk" data that would not be of sufficient quality to warrant submitting to the FDA, much less submitting to the FDA with any chance of obtaining approval. Even so, he questioned how to deliver the bad news to the Executive Committee. He then commented that he did not want to state the true nature of the Rummel and BRIGHT studies in the slide deck because "this stuff lives forever"—an apparent concern, given the Cephalon's recent settlement

with the Government, that the truth about the Company's lack of confidence in the Rummel and BRIGHT studies would come out in response to a Government subpoena.

103. VP Campbell then asked VP Wilkins if Dr. Lesley Russell, a Cephalon Executive Vice President, its Chief Medical Officer and a member of the Executive Committee, was aware of the studies' flaws. VP Wilkins responded that Dr. Russell was in fact aware of the problems with Rummel and BRIGHT, and that she would not be surprised to hear of the "high risk" designation from VP Campbell.

104. It is telling that Dr. Russell, an Executive Committee member who, according to her online biography led "Cephalon's global clinical, medical, regulatory, drug safety, and biometrics organizations," allowed the Company to continue its off-label promotion of Treanda® based on the Rummel study's result while knowing that its underlying clinical data was inadequate to support the efficacy and safety claims being made to the oncology community.

105. During this same Long-Range Planning meeting, Senior Director of Regulatory Affairs Marchione explained that the FDA had specifically required Cephalon to obtain more safety data on Treanda® before submitting a front-line application. For example, the FDA had required cardiac safety studies to ensure the absence of QT prolongation, which can cause a fatal arrhythmia, torsades' de pointes. In addition, the FDA required that Cephalon conduct and submit toxicology studies, pharmacokinetics studies and other analyses to protect patient safety in the front-line setting. Marchione acknowledged that this safety data was not available for the Rummel study, nor would it be forthcoming—an apparent reference to the study's inadequate collection of safety data. All this data would be necessary before the FDA would approve exposure of the much larger front-line iNHL patient population to the Treanda®, Marchione said.

106. At this point, VP Campbell concluded the discussion by characterizing the consensus decision to continue the BRIGHT study as only a "mitigation strategy" that effectively allowed the Company cover so that it could continue its off-label promotion of Treanda® without having to publicly acknowledge the inadequacy of the existing data to support its front-line use.

107. Agreeing with this characterization, VP Wilkins then shared his view that this mitigation strategy worked because the PFS data from the BRIGHT study would not become available until after Treanda® had lost its marketing exclusivity in 2015, when Cephalon would no longer be actively marketing the drug. As such, negative results from BRIGHT would come too late to hurt sales of Treanda®. Critically, Wilkins' comment expressed such a doubt in the reliability of the Rummel study that he believed it was likely that the BRIGHT study would "go the other way."

108. All of the senior leaders in the room at this point in the meeting agreed that they privately considered it a "high risk" (i.e., great likelihood) that both the Rummel and BRIGHT studies lacked the quality necessary to submit them for approval of a front-line iNHL indication, but they agreed to state on the PowerPoint® slide for the Executive Committee that it was only a "medium risk" in order to avoid any possibility that the slide could later be used to challenge the Company's confidence in the strength of the Rummel and BRIGHT studies.

109. While the discussion of "risk" at times referred to the risk that the studies would be insufficient to obtain final FDA approval for Treanda®, the discussion of the specific language to include on the slide specifically referred to the "risk" that submission of a front-line sNDA would result in a refusal-to-file decision (*see supra* ¶¶ 37-41)—i.e., the threshold facial review that occurs before the FDA allows an sNDA to be officially filed and proceed to a more substantive review.

110. That this discussion of "risk" regarded not just the risk that the Rummel and BRIGHT Studies would fail to merit a front-line indication for Treanda®, but that the studies would fail even to meet the FDA's threshold criteria for consideration, demonstrates the seriousness of the flaws in both the Rummel and BRIGHT studies. The long-range planning discussion of the draft slide makes clear that the senior managers involved perceived the studies to be fundamentally flawed that there was a good chance they would not even survive a preliminary facial review, let alone full substantive review, by the FDA.

111. The Long Range Planning meeting thus elucidates the deception and fraudulent conduct underlying the Company's off-label promotion of Treanda®. Privately, Cephalon's senior executives acknowledged that the primary purpose of the BRIGHT study was *not* to obtain a new FDA indication (which the Company knew was out of reach), but rather was to provide a "Pope-like" "veil" of good-faith effort by the Company. Cephalon could then use this veil to deceive anyone who might challenge its off-label promotion of Treanda®, including the FDA, Compendia publishers, physicians, patients and their families.

112. Theses frank internal discussions reveal that Cephalon has known that the Rummel and BRIGHT data would not support such off-label use, but devised a scheme whereby merely conducting the studies would protect the Company against later charges that it had intentionally peddled ineffective, and almost twenty times more expensive, therapies to an unwitting public. Cephalon considered the BRIGHT study to be an exercise in *risk mitigation*, rather than scientific discovery, and deliberately took measures to conceal that information from the medical community, patients, and the Government.

113. Perhaps most disturbing, during the Long Range Planning Committee meeting these Cephalon executives privately stated that this risk mitigation strategy was a "low risk"

proposition for the Company. This is because, by the time any negative progression-free survival data from the BRIGHT study would be made public, Treanda®'s market exclusivity will have expired and Cephalon will already have obtained its illicit gains from its off-label scheme. Clearly anticipating a negative outcome, VP Wilkins even went so far as to say that the PFS data for BRIGHT is "gonna kill us."

114. If ever challenged, the plan was to say that the Company believed the study data provided hope for a future FDA-approved front-line iNHL indication. However, this representation is knowingly false.

C. Cephalon's False and Misleading Off-Label Promotion of Treanda®

115. To promote Treanda® off-label for front-line use and gain market share prior to the expiry of Treanda®'s market exclusivity in 2015, Cephalon leveraged an array of off-label promotional methods, including sales representative details, speaker programs, improperly influenced continuing medical education, advisory boards, in-practice programs, and sham market research studies. In each instance, Cephalon's off-label promotion was not only illegal, but also substantially misleading because it presented the Rummel study as definitive evidence of Treanda®'s effectiveness and superiority versus R-CHOP for front-line treatment of iNHL without disclosing the study's significant flaws and the belief of Cephalon's own executives that those flaws produced substantial uncertainty as to the veracity of the study's result.

1. Pre-Launch Promotion of Rummel Study

116. Even before Treanda®'s launch, Cephalon promoted to the oncology community and investors that the Rummel study would inaugurate Treanda® as the new standard of care for front-line treatment of iNHL. On December 10, 2007, nearly a year before Treanda® was even approved to treat second-line iNHL, Cephalon held an earnings call at the annual meetings for

the American Society of Hematologists ("ASH"), the world's largest and most influential professional society of hematologic oncologists, to preface the launch of Treanda®. The presenters included Dr. Rummel himself, who gave a preeise of interim results for his study, and Dr. Bruce D. Cheson of Georgetown University, a paid Cephalon consultant who unabashedly discussed the Rummel Study and 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. Sales Representatives Promoted the Rummel Study as Evidence of Treanda®'s Effectiveness for Off-Label Front-Line Use

117. Cephalon's off-label promotional scheme accellerated following the prsentation of the final Rummel study results at ASH 2009. During his presentation, Dr. Rummel proclaimed that the bendamustine-rituximab combination "has the potential to become a new standard front-line treatment option for patients" with iNHL.

118. During the week of December 14-18, 2009, Cephalon's Marketing Department held a WebEx seminar to train the Treanda® sales force on the Rummel study data. While the training was purportedly "for educational purposes only," this caveat was intended only to create a façade of legal compliance, and the message to sales representatives was clear that they should begin promoting the Rummel study as a basis for physicians to prescribe Treanda® for front-line treatment of iNHL. The presentation to sales representatives did not disclose the flaws of the Rummel study, and sales representatives in turn did not disclose these flaws to physicians.

119. On March 1, 2010, at the Annual Sales Meeting in San Diego, Cephalon reiterated to its oncology sales force that it should leverage the Rummel study to drive front-line sales. In attendance were 92 oncology sales representatives, 12 area managers, 2 regional directors, and a

number of national managers. The purpose of the meeting was to introduce new promotional pitches, announce sales objectives for 2010, and build morale within the sales force.

120. Craig Phillips, the Vice President for the Oncology Business Unit, began the meeting by announcing to the sales force that Cephalon was poised for a successful year of high Treanda® sales because of the "great new data" from the Rummel Study. Phillips' statement created excitement within the sales force, which understood that Cephalon's and 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. Phillips did not disclose that the Rummel study concerned off-label use of Treanda®, nor did any of the other managers in attendance take corrective action to make clear that use of the Rummel study to promote Treanda® for off-label front-line use was illegal.

121. On the contrary, Cephalon had previously made clear to sales representatives that they should use all available tactics to increase sales of Treanda® and that off-label promotion was a necessity to meet their sales quotas. During the April 2008 launch meeting for Treanda, held in Tampa, Florida, Vice President and General Manager of the Oncology Business Unit Elizabeth Barrett told 100 gathered sales representatives and senior managers that Treanda® offered an opportunity for huge bonuses and that the Company's annual sales forecasts reached $500 million a year.

122. Cephalon's sales forecast grossly exceeded the market for not just what was then Treanda®'s only indication, CLL, but also grossly exceeded the market for the indication it would receive six months later for second- and third-line treatment of iNHL. The only possible way to achieve that target was through off-label promotion of Treanda® for front-line iNHL, making clear that Cephalon's promotional strategy for Treanda® centered on off-label front-line

promotion even 18 months prior to release of final results from the Rummel study and one year prior to its initiation of the BRIGHT study.

123. To emphasize to sales representatives their opportunity to profit by driving sales of Treanda®, Barrett arranged to have waiters burst into the launch meeting carrying trays full of actual $50 bills. The waiters circulated throughout the room and representatives were encouraged to grab fistfuls of money. While they did so, Barrett told the sales force that selling Treanda® would be "like taking free money."

124. The flagrance of this event is all the more outrageous since Cephalon had, only several months earlier, entered into an agreement with Department of Justice prosecutors to settle allegations regarding its off-label promotion of Actiq®, Provigil®, and Gabitril®, and was in the process of negotiating the terms of its five-year Corporate Integrity Agreement. Other senior managers in attendance included Bob Roche (Executive Vice President for Worldwide Operation), Craig Phillips (Senior Group Director, Sales and National Accounts), and Dan Relovsky (Marketing Director, Oncology).

125. By basing its quota and bonus programs for sales representatives on its off-label sales projections, Cephalon required sales representatives to sell off-label by setting targets so high that they were unachievable through on-label promotion alone. At all times material hereto, the only way the sales representatives could meet the quotas was to promote Treanda® off-label.

126. An internal document entitled "Oncology: First Semester 2011: Bonus Plans," dated September 21, 2010, sets forth the 2011 bonus structure for sales representatives, area managers, and regional directors, and describes that bonuses will be based on a Treanda® sales goal of $502 million—an unattainable figure if the Treanda® were limited to on-label sales. The on-label opportunity for Treanda®—excluding any combination therapies, which Cephalon's

Regulatory Affairs department has deemed outside Treanda®'s labeled indication—is only about 5% of that amount.

127. By meeting Cephalon's excessive sales quotas, sales representatives stood to gain massive bonuses of $48,000 (on top of their average salary of $112,000); area managers, $72,000 (in addition to their average salary of $150,000); and regional directors, $86,000 (in addition to their salary).

128. As a result of Cephalon's training and bonuses, Cephalon's sales representatives have promoted Treanda® off-label for front-line iNHL, as evidenced in the Company's own message recall surveys, which Cephalon was required to conduct as part of its CIA. The audits were performed by a third-party contractor, ZS Associates, which surveyed physicans who had been detailed by a Cephalon oncology sales representative. As part of his job duties, Relator Cestra received and reviewed a message recall audit report from the first quarter of 2011, including both a slide deck summarizing the audit results (Q1'11 TREANDA Compliance Scoring - All Respondents (n=100)04.18.11 v2.0.....pptx) as well as an Excel spreadsheet containing the raw responses (Q1'11 TREANDA Compliance Scoring - All Respondents (n=100)04.18.11 v2.0.xls).

129. The slide deck and presentation demonstrate that Cephalon's sales representatives promoted the Rummel study as evidence of the effectiveness of Treanda® for off-label, front-line treatment of iNHL. The following verbatim responses, from physicians who were asked to summarize the message delivered by Cephalon's sales representatives, provide a sample of sales representatives' off-label promotion:

- "use of frontlien (sic) rx in patients with low grade lymphomas" (Response ID no. 565);

- "Combination treatment with Rituximab for NHL patients" (Response ID no. 27);
- "use with Rituxan in first line" (Response ID no. 622);
- "study showing r chop vs treanda rituxan with comparable efficacy and less toxicity and tolerability" (Response ID no. 379);
- "Minly (sic) discussed trial data comparing rituxan-treanda to rituxan -chop in follicular NHL" (Response ID no. 386);
- "We discussed the Rummell (sic) data detailing the use of BR as first line treatment for low grade FL" (Response ID no. 451);
- "efficacy of treanda with rituxan in . . . nhl" (Response ID no. 425);
- "You can take it any line of therapy in any combination" (Response ID no. 456);
- "German trial comparing R-CHOP vs BR" (Response ID no. 491);
- "again use in cll and non hodgkins lymphoma. discussed how the community uses it with rituxan" (Response ID no. 525);
- "as effective as r chop in indolent nhl" (Response ID no. 520);
- "br as the first line low grade" (Response ID no. 528); and
- "use . . . upfront tx for follicular NHL" (Response ID no. 536).

Cephalon has in its possession, or can readily obtain from ZS Associates, the documents necessary to identify which sales representatives delivered these off-label promotional messages and the physicians to whom they were delivered.

130. Despite the prevalent evidence of off-label promotion produced by Cephalon's message recall surveys, the results nonetheless substantially understate the actual incidence of

off-label promotion. ZS Associated used sales representatives' call notes as its basis to identify recent sales calls and select physicians to survey. When sales representatives learned as much, they stopped entering call notes for calls where they had engaged in off-label promotion, resulting in a precipitous drop in the total number of sales calls logged.

131. On September 20, 2010, during a national sales meeting in Dallas, Relator Cestra attended a presentation by Craig Phillips, then Cephalon's Vice President for the Oncology Business Unit, to the Company's oncology sales representatives and executives. VP Phillips told those present that Cephalon's Executive Committee and Compliance Department believed the supposed decrease in both on- and off-label sales calls did not reflect reality. Instead, this reflected management's belief that sales representatives had stopped logging off-label sales calls after learning that the calls were being audited pursuant to the existing Corporate Integrity Agreement. It was apparent that the sales force was circumventing the system put in place to audit off-label misbranding activity in order to avoid being identified in a subsequent internal audit.

132. As a result of Cephalon's sales representatives' off-label promotion of Treanda®, physicians prescribed Treanda® for front-line use and submitted false claims to Government health care programs for reimbursement.

3. Co-opting of Continuing Medical Education Programs to Promote Treanda® for Off-Label Use

133. Another key tactic employed by Cephalon following the ASH 2009 presentation of the final Rummel study results was the improper manipulation of continuing medical education ("CME") programs as promotional tools to promote Treanda® for front-line use.

134. CME courses are required 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 May 26, 2013). 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).

135. Cephalon knew that its manipulation of CMEs into promotions for off-label use of Treanda® was illegal. In a July 24, 2009 slide deck for its Oncology Integrated Business Plan, Cephalon acknowledged that using CMEs as promotional vehicles for the off-label use of Treanda® was prohibited. In fact, the Treanda® Brand Team included these restrictions among the "threats" to Treanda® sales growth: (i) "CME Guidelines"; and (ii) "government restrictions on promotional practices."

136. Nevertheless, Cephalon has routinely used CMEs as promotional tools to promote the Rummel study as clear evidence of Treanda®'s effectiveness for front-line use, while withholding critical information about the Rummel study's deficiencies. During the same presentation, the Brand Team identified several priorities in order to "establish Treanda as the cornerstone of chemotherapy in hematologic disease," which included the need to "satisfy unmet education need with CME" and to "explore new data dissemination opportunities." The "new data" to which the presentation referred was the Rummel study.

137. For example, at ASH 2009 where the final Rummel study results were presented, a paid Cephalon consultant presented a CME program in which he touted the Rummel study results and advocated the use of Treanda® for front-line treatment of iNHL. The consultant,

Richard Van Etten, wrote prior to the ASH conference on December 1, 2009 that "looks as if [Treanda®-Rituxan®] will become a standard" in the front-line treatment of iNHL.

138. Following ASH, Van Etten again promoted Treanda® for front-line use based on the Rummel study's results in an interview, portions of which were published by Medscape on December 9, 2009. During the interview, Van Etten promoted the Rummel study as "potentially practice-changing data." Although he wanted to see "a confirmatory study" and "overall survival results," he did not "think we need to wait for that" to begin prescribing Treanda® as front-line treatment. There is no indication that Dr. Van Etten disclosed his financial ties with Cephalon either when he made these remarks to Medscape, or during his presentation at the ASH 2009 conference. In doing so, he created the misimpression that his opinions were independent and not influenced by his financial ties to Cephalon.

139. Following ASH 2009, Cephalon significantly expanded its use of CMEs to promote Treanda® off-label by shifting the emphasis of its promotional activities from officially Company-sponsored speaker programs, which many physicians intentionally avoid, to CME programs, which physicians prefer both because they are able to fulfill their CME requirements and because the programs are supposedly free of drug-manufacturer influence. By relying on third-party CME vendors to facilitate the programs, Cephalon was also able to more easily promote Treanda® off-label while concealing its own influence.

140. To fund the CME promotional blitz, shortly following ASH 2009 Cephalon transferred $2 million dollars from the Sales and Marketing Department, where the money had been allocated for promotional speaker programs, to the Medical & Scientific Affairs Department, where it was redesignated for CME programs. The transfer was initiated by Craig Phillips, Vice President for the Oncology Business Unit, and later approved by Cephalon's

Executive Committee. Such a transfer from Sales and Marketing to Medical Affairs was highly unusual, but it served to allow Cephalon to promote Treanda® for front-line use through CME programs, whereby it was able to evade promotional restrictions on official company-controlled programs and simultaneously reach a larger audience. The purpose of these CME programs was thus blatantly promotional.

141. When Phillips announced the transfer of the $2 million to the sales force, sales representatives initially expressed disappointment that the removal of funds would take away speaker monies they could have used to promote the Rummel data. VP Phillips subsequently explained that sales representatives need not worry, that the CME programs would be a more effective avenue for promotion of Treanda® and would generate a better return on investment than would the speaker programs.

142. Cephalon thus knowingly and illegally used CME programs as marketing vehicles and calculated revenues generated directly from these programs accordingly.

143. The CME programs that Cephalon funded through the $2 million transfer of Sales and Marketing funds included:

- Two paid Cephalon consultants, Drs. Bruce Cheson and John Leonard used the Rummel study to promote Treanda® off-label for the front-line treatment of follicular lymphoma in a CME entitled "2009 ASH Update on Hematologic Malignancies: Indolent Lymphoma," which was posted on Medscape.org on February 12, 2010.
- Dr. Rummel, who was himself a paid Cephalon consultant, led a Cephalon-funded CME in which he stated that Treanda® plus rituximab 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 told the audience that the B-R regimen is the standard treatment in Germany where "all" German private practitioners use Treanda® in the front-line treatment of iNHL, encouraging the attendee oncologists to do the same.

- 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 CME article titled "Managing High-Risk Patients With Non-Hodgkin's Lymphoma: Two Cases," which was posted on Medscape.org on April 13, 2010.
- At the 2010 American Society of Clinical Oncology ("ASCO") meeting, held in Chicago from June 4-8, 2010, Cephalon sponsored a CME Satellite Symposium that included off-label promotion of Treanda® for front-line use.

144. Cephalon controlled the content of the CME events that it sponsored to ensure that they favorably presented Treanda® and advocated it as front-line treatment for iNHL. For example, at the end of May 2010, approximately one week before the Cephalon-sponsored satellite CME at ASCO, Cephalon's Senior Director of Marketing, Matt Shaulis, spoke directly with Neil Love, owner of the CME provider Research to Practice, who was slated to moderate the symposium. Shaulis ensured that Love planned to include a favorable off-label message for Treanda® as front-line treatment for iNHL, which Love subsequently did.

145. Although Research to Practice describes itself as a "medical education company..., specializing in physician and allied health professional education focused exclusively on oncology and hematology" with programs containing "unbiased educational

perspectives," *see* http://www.researchtopractice.com/about-us (last visited Aug. 21, 2010), its Cephalon-sponsored CME programs were influenced by Cephalon and subject to its commercial bias.

146. Cephalon exerted control over another CME program facilitated by Research to Practice titled "Hematologic Oncology Update Think Tank 2010," which as a result of Cephalon's influence recommended Treanda® for front-line treatment of iNHL. In preparation for the program, Cephalon Marketing personnel provided Research to Practice the names of three key opinion leaders ("KOLs"), who were proven advocates of off-label front-line use of Treanda®, for Research to Practice to use as speakers for the program. Cephalon also 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 and ensure favorable portrayal of Treanda® as it was being recorded.

147. Cephalon's corruption of CME programs as promotional vehicles violated applicable industry standards, FDA rules and regulations, as well as its own internal guidelines for conducting CMEs. As part of the scheme, Cephalon sponsored and unduly influenced numerous such CME programs that, as a result, served as promotional messages for the front-line use of Treanda® to treat iNHL.

148. After Relator Cestra reported to the Compliance Department his concerns regarding the improper $2 million transfer, Cephalon purported to erect a firewall between the Sales and Marketing and Medical and Scientific Affairs divisions; however, this separation served as a firewall on paper only. In reality, the Sales and Marketing department continued to exert influence over the content of Cephalon-sponsored CME programs to ensure that they recommended Treanda® off-label for the front-line treatment of iNHL. None of these programs

disclosed what Cephalon knew to be the significant flaws with the Rummel study, and the programs were therefore misleading.

149. As a result of Cephalon's co-opting of CME programs as promotional tools, oncologists prescribed and submitted false claims for reimbursement of Treanda® for front-line use to Government health care programs.

4. Off-Label Promotion of Treanda® Through Speaker Programs

150. A key reason that Cephalon favored CME programs as vehicles for its off-label promotion of Treanda® was the heavy regulation of speaker programs funded and conducted by pharmaceutical companies. Official company-sponsored promotional presentations must be "on-label" and must contain a "fair balance"—i.e., a discussion of the risks and benefits of the drug, including adverse effects, precautions, and warnings. Above all, promotional programs must be truthful and not misleading.

151. Nevertheless, beginning after the Treanda® launch in 2008, the Oncology sales force set up hundreds of speaker programs for healthcare professionals at which off-label promotional presentations flouted the FDA rules regarding such presentations. The programs were rife with illegal promotional activities.

152. The following are examples of speakers who Cephalon's Oncology sales force retained in order to promote Treanda® off-label for the front-line treatment of iNHL:

- Dr. Zale Bernstein, an oncologist from Buffalo, New York gave 38 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $89,650.
- Dr. David Rizzieri, a hematologist/oncologist from Durham, North Carolina gave some 39 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $200,150.

- Dr. Maureen Cooper, a hematologist from Durango, Colorado gave 18 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $119,700.
- Dr. Dan Douer, a hematologist from Los Angeles, California gave 11 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $133,200.

153. In the summer of 2010, Cephalon created a promotional speaker slide deck that promoted Treanda® off-label for the front-line treatment of iNHL. The slide deck was prepared by Cephalon's Marketing Department and approved by the Company's Legal, Regulatory and Medical Affairs Departments (i) for use in training Cephalon's paid promotional speakers, and (ii) for use by Cephalon's paid promotional speakers themselves when delivering Cephalon-sponsored presentations to physicians, including the large audiences associated with GPOs' In-Practice Programs, discussed *infra*.

154. The slide deck, entitled "TREANDA® (bendamustine HCL) for Injection: A Unique Treatment for Patients with Indolent B-cell Non-Hodgkin Lymphoma that has progressed" and internally dated August 12, 2010, provides an overview of iNHL, a general background on Treanda®, as well as a review of clinical studies involving the drug. But the on-label promotional material quickly gives way to off-label promotion of Treanda®. Specifically, the slide deck incorporates "therapeutic options" set out in the NCCN Clinical Practice Guidelines for treatment of follicular lymphoma (a form of iNHL), which recommends Treanda® plus Rituxan®, based on the Rummel data.

155. Cephalon's misleading promotion of the Rummel study through promotional speaker programs not only violated FDA regulations prohibiting off-label promotion but caused

physicians to prescribe Treanda® for off-label front-line use and thereby caused the submission of false claims to Government health care programs.

5. Advisory Boards to Promote Treanda® for Off-Label Front-Line Use

156. Cephalon regularly held so-called "Advisory Boards" at which it paid physicians $4,000 per day in order to be able to promote Treanda® to them for front-line treatment of iNHL. Although the official purpose of the Advisory Boards was to share scientific information between Cephalon and healthcare professionals with expertise in treating iNHL, as well as to solicit the health care professionals' advice as to the effectiveness of Cephalon's promotional messaging, in reality the Advisory Boards were thinly veiled promotional vehicles for off-label front-line use of Treanda®. As discussed *infra*, the Advisory Boards also served as kickback to the attendees, who not only received $4,000 honoraria but what were in essence vacations at lavish resorts.

157. Tellingly, the Advisory Boards were run by Cephalon's Marketing Department, not by its Medical Affairs division. Physician attendees were nominated to attend by the Company's Sales and Marketing staff, not based on those physicians' expertise, but based on their potential to prescribe large quantities of Treanda® for the front-line treatment of NHL.

158. To drive home the off-label message, Dr. Rummel presented his flawed Treanda® at many of the advisory boards. Attendees were then invited to comment on whether they would use Treanda® in treating their patients. What was missing from the presentations at the advisory boards was what Cephalon internally knew to be the flaws with Dr. Rummel's study.

159. The quantity of Advisory Boards that Cephalon conducted was far in excess of the number legitimately required to obtain physician advice about Treanda®. The Company has generally conducted multiple Advisory Board meetings each quarter of the year, some of which

have been attended by as many as 60 oncologists, which grossly exceeds the industry norm of 10 to 15 attendees.

160. As a final indication that the purpose of the Advisory Boards was promotional, Cephalon carefully monitored the "return on investment" or "ROI" of the Advisory Boards, based on increase in prescribing of Treanda® by the attendees. For example, a July 22, 2010 "Treanda® Brand Review" slide deck described the "High Efficiency" of the Company's marketing tactics and stated that year-to-date Advisory Board spending of $826,000 had an ROI 8 to 1 – a "return" of nearly $5 million in new, off-label sales of Treanda®.

161. The "Treanda® Brand Review" slide deck also demonstrates that Cephalon's use of Advisory Boards as off-label promotional vehicles has been highly effective, and that as a result of Cephalon's off-label promotion physicians have prescribed Treanda® for off-label use, resulting in the submission of false claims to Government Programs.

6. Sham Market Research Studies to Promote Treanda® Off-Label for Front-Line iNHL

162. Another Post-ASH 2009 tactic employed by Cephalon was to leverage sham market research studies to promote the Rummel study to oncologists.

i. Dynamic Practice Simulation Questionnaire

163. Shortly after the ASH 2009 conference at which the final Rummel Study data were presented, Cephalon recruited 100 oncologists and hematologists based on the number of newly diagnosed (i.e., front-line) iNHL patients they treated, to participate in a survey that ostensibly 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 Treanda off-label to physicians who had not attended the conference. The express purpose of the questionnaire was to promote Treanda® off-label for front-line use to carefully-selected physicians in a captive context while they were paid for their time.

ii. **NCCN Market Research Study**

164. Cephalon paid the influential NCCN (which publishes one of the CMS-approved drug Compendia on which Medicare and Medicaid payment is based) to disseminate a sham market research study in order to "seed" the notion at NCCN and to its members that the Rummel Study data supported the off-label use of Treanda® in combination with rituximab for front-line treatment of iNHL. As a high-level sponsor of the NCCN, Cephalon was afforded the opportunity to conduct market research with NCCN's physician members and, in this instance, leveraged the opportunity to promote the Rummel study to 448 of NCCN's members. The survey, which was conducted in June 2010 and titled "NCCN Trends," purported to be "an analytics tool" that "surveys how clinicians across the U.S. and around the globe are delivering cancer care." The survey was specifically targeted at physicians treating hematologic malignancies and was completed by 448 "users of NCCN.org" in the United States and abroad.

165. After preliminary questions confirming the survey participants' involvement in the management of cancer care, page three of the survey asked participants how many patients for whom they had, over the past three months, prescribed certain therapies for iNHL "induction therapy"—i.e., front-line treatment of iNHL. Treanda® plus rituximab was among the five treatment options. (Sixteen percent of physicians responded that they use this off-label Treanda® combination therapy.) The next question specifically asked: "For those patients in the above

situations who you chose to treat with bendamustine, what are the reasons for selecting this therapy?" Two of the available answers are "New Clinical Trial Data" and "Progression-free Survival Data," both of which are references to the flawed Rummel study. The survey abruptly ends after that question, never asking about reasons for using any of the other treatment regimens (nor disclosing any of the Rummel flaws), but plainly advising the 448 NCCN respondents that there is new data that purportedly supported the use of Treanda® for front-line treatment of iNHL.

166. Cephalon paid NCCN to disseminate this study. Indeed, Kathy Roman, Associate Director of Cephalon Oncology's Strategic Analysis & Planning, at the time explained in an email that accompanied the study: "In exchange for our NCCN sponsorship we are entitled to field a four question survey through the NCCN Trends analytics tool." Dave Aspesi, the Treanda® Marketing Director, devised the three Treanda®-related questions. Ms. Roman explained in her email that future study participants "will receive a final version of the attached summary results that offer insight into their own practices." As such, Cephalon used its financial sponsorship of NCCN as an inducement to promote Treanda® off-label and to influence the NCCN Compendia to support its off-label use.

iii. **Patient Share Research Study**

167. In February 2010, Cephalon commissioned a market research study that it used to expose 154 key oncologists to the Rummel Study data immediately following ASH 2009. As described in a February 2010 PowerPoint slide deck titled "TREANDA® Patient Share Research For Indolent NHL Treatment," the survey's objectives included assessing the "Impact of Future Events on TREANDA Share for iNHL1" (i.e., front-line iNHL). The research study presented 154 participating physicians with a total of 15 different, but cumulative, future-event profiles

(depending on treated patient types). Immediately following each event profile, physicians were asked how the information would change their treatment allocations, if at all, and they were given the opportunity to change those allocations. The future event profiles for physicians treating front-line iNHL patients included: (1) "TREANDA label + Rummel PFS at 3 yrs (presented at ASH 2008)"; "Availability of TREANDA + Rituxan vs. CHOP-R PFS data"; and "FDA Approval of TREANDA + Rituxan in NHL-1."

168. Slide 6 of the deck demonstrated the impact of the Rummel data and Cephalon's off-label promotion on Treanda®'s front-line market share for iNHL. Specifically, the research study's results demonstrated a 23% increase in market share from the Rummel data and an additional 6% increase from a comparative analysis study between the Treanda®-Rituxan® combination and CHOP-R.

169. As such, Cephalon used this market research study, as it has used other similar studies, to expose high-prescribing physicians to the off-label and deeply flawed Rummel study. The market research study also reveals Cephalon's awareness that its off-label promotion of the Rummel study had increased Treanda®'s market share for this off-label use.

iv. **DLBCL Market Research Study**

170. In January 2011, Cephalon employed yet another bogus market research study to promote Treanda® off-label for the treatment diffuse large B-cell lymphoma ("DLBCL"). DLBCL is an aggressive lymphoma that accounts for approximately 40% of lymphomas among adults. Thus, although Treanda® is not approved by the FDA for the treatment of DLBCL, Cephalon covets the market due to its size.

171. The results of that market research study were reported in a January 2011 presentation titled "Treanda® Patient Share Research for DLBCL Treatment," which confirms,

for example on page six, that Cephalon used the guise of a market research study to "educate" physicians on the pertinent off-label data, and then prodded the physicians towards such off-label use by asking them specific questions about how that data would impact their future treatment decisions. Cephalon's disclaimers notwithstanding, this was little more than a brazen act of off-label promotion aimed at deceiving oncologists into believing the Rummel study was a sufficient basis for them to change patient care, when in fact Cephalon knew at the time that the data were not adequate to support this conclusion.

172. Cephalon thus knew that physicians' exposure to data in Cephalon's off-label market research studies caused those physicians to treat their front-line iNHL patients off-label with Treanda®. Moreover, the market research studies' results confirm that Cephalon's strategy was to grow Treanda®'s market share through an off-label promotional strategy, rather than through the costly and time-consuming process of obtaining FDA approval. Cephalon's use of market research studies to promote Treanda® off-label for front-line use caused physicians to prescribe Treanda® for that use, and as a result, caused the submission of false claims to Government health care programs.

7. False and Misleading Minimization of Safety Risks

173. While Cephalon's off-label promotion of Treanda® has focused primarily on claims of Treanda®'s superior efficacy versus R-CHOP for front-line treatment of iNHL, Cephalon's off-label promotion has also included misleading minimization of Treanda®'s safety risks in order to further them impetus for physicians to prescribe Treanda® in the front-line setting.

174. 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 division was subsequently renamed the Office of Prescription Drug Promotion.) 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).

175. The second Warning Letter, dated December 18, 2009, cited Cephalon for improperly promoting Treanda® through dosing cards that omitted critical risk information, including that Treanda® "is associated with numerous serious risks, some of which can be fatal." The dosing card, however, 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."

176. Cephalon's misleading minimization of safety risks is particularly relevant to, and concerning, given its off-label promotion of Treanda® for front-line treatment of iNHL where Treanda®'s safety profile remains ill-characterized. As noted *supra*, ¶¶ 84, 86, inadequate recording of adverse events was one of the Rummel study's key flaws, and the FDA expressed concern about the lack of data supporting the long-term safety of the Treanda®-Rituxan® regimen. Cephalon's promotion of the Rummel study therefore necessarily entailed an incomplete description of Treanda®'s risks, which is made all the more concerning by the Company's knowing concealment of those risks that have been well characterized.

177. Cephalon, however, has continued to misleadingly downplay Treanda®'s safety risks. During a Brand Team meeting in November 2010, Jim Sterchele, Cephalon's Senior Director of Medical Information within Oncology Medical Affairs, announced that incidents of extravasation, one of the serious side effects of Treanda® in which cancerous cells exit the capillaries and enter organs, had been reported as post-marketing adverse events at a more alarming rate than expected. Sterchele identified this development as a public relations "issues management" concern, rather than as a safety concern.

178. Cephalon's misleading minimization of Treanda®'s safety profile contributed to the effectiveness of its promotion of Treanda® for front-line use, and by doing so caused physicians to prescribe Treanda® for treatment of front-line iNHL and the subsequent submission of false claims to Government health care programs.

D. Cephalon Filed Front-Line sNDA, Despite Knowing That the FDA Would Not Approve It, to Misleadingly Bolster Confidence in the Rummel Study

179. Because the Company's off-label promotional campaign has been so successful, Cephalon knew that approval for front-line use would only add marginally to Treanda®'s sales. During a July 22, 2010 Treanda® Brand Review meeting among senior executives, which

included Chairman Frank Baldino, the CFO, the entire Executive Committee, and multiple vice presidents from the clinical development team, Baldino questioned why the Company purported to pursue FDA approval for front-line use when Treanda® was already being reimbursed for that use by most payors. When Senior Director of Strategic Analysis, Vlad Vitoc, 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, Baldino queried why Cephalon would continue to fund the BRIGHT study at a cost of roughly $60 million 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.

180. The answer of course, as discussed among senior executives during the Long-Range Planning meeting, *see* ¶¶ 92-114, is that the BRIGHT study, coupled with the Company's façade of pursuing a front-line indication misleadingly, bolsters physician confidence in the Rummel study, and it deflects Government concern regarding its off-label promotion of Treanda® for front-line use. Internally, Cephalon executives have acknowledged that both the Rummel and BRIGHT studies are wholly inadequate to obtain FDA approval for Treanda®'s front-line use.

181. Nonetheless, during an earnings call on May 10, 2010, Baldino, told investors, "[w]e 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).

182. A year later the new CEO, Kevin Buchi, espoused the same message:

> We remain on track in our efforts to expand the label with our program to secure a front-line indication for TREANDA in

> Indolent Non-Hodgkin's Lymphoma. Following the completion of extensive data monitoring, we plan to file the Steel [sic] Group's study with the FDA around the middle of this year. Furthermore, as mentioned earlier, our own front-line study continues to progress. We remain confident that TREANDA will continue to grow within its current indications, and also has the potential for expanded utility based upon the outcome of ongoing clinical trials.

See Cephalon Q4 2010 Earnings Call, February 10, 2011, *available at* http://seekingalpha.com/article/252254-cephalon-s-ceo-discusses-q4-2010-results-earnings-call-transcript. Asked during the question and answer session about the prospects for gaining front-line growth in the absence of FDA approval, Buchi responded that the

> combination of the Steel [sic] data and the Phase-III program that we are running in front-line therapy, we do very much hope that we will be able to get that indication in the not-too-distant future.

Id.

183. CEO Buchi's emphasis on the Rummel Study and the BRIGHT Study was the product of talking points circulated before the call, which were developed and approved by Cephalon's Acting Vice President for Oncology, Bill Campbell, and its National Sales Director, Matthew Shaulis, and emphasized Cephalon's supposed intention to seek a front-line indication.

184. There was therefore a significant disjunction between Cephalon's public pronouncements that it sought and expected to receive a front-line indication and its internal belief in the impossibility thereof. Although by August 2011 Cephalon's senior management was fully aware that the Rummel and BRIGHT studies were insufficient to support an application for a front-line indication for Treanda®, they nevertheless continued to take steps toward filing an sNDA as an act of mitigation.

185. Around this time, Fred Vitale, Cephalon's Director of Oncology Marketing, expressed discontent that as part of his preparation of the Treanda® business plan, he was

required by the Company to set aside money for a front-line sNDA. Even though Vitale did not want the front-line application in his budget or think it was necessary to include it, his managers insisted that the Company still needed to allocate money to the front-line sNDA in order to maintain the appearance that it expected that the sNDA application would be approved.

186. Thus, Cephalon continued to pursue a front-line indication for Treanda® with the express intention of misleading healthcare providers, patients and their families, and the Government into believing that Treanda® was more effective for the front-line treatment of iNHL than Cephalon knew had been reliably demonstrated.

187. Cephalon finally filed its sNDA on December 29, 2011. The Company sought to file the application by the end of 2011 for two reasons: first, Cephalon sought to maintain the appearance, per its public pronouncements, that it had always intended to seek an indication. The second was because Cephalon's regulatory managers, including Lesley Russell, would achieve an additional metric used to calculate bonus payments and thus receive significantly higher bonuses by doing so.

188. As Cephalon's management expected, the FDA regarded the Rummel study coupled with CR data from BRIGHT as insufficient to approve Treanda® for front-line use. The FDA notified Cephalon that in order for its sNDA to be approved the Company would need to provide PFS data from BRIGHT to substantiate the Rummel study's result. As PFS data from BRIGHT will not be available until 2015, the FDA effectively denied the Treanda® front-line application.

E. Interim BRIGHT Results Signal Problems with Rummel

189. On December 11, 2012, Dr. Ian Flinn presented interim results for the BRIGHT Study at the annual ASH meeting in Atlanta. The results, both with regard to efficacy and safety,

diverged in important respects from those of the Rummel study and added increased uncertainty to the reliability of the Rummel study's results. As one commentator wrote with regard to BRIGHT's preliminary PFS and OS data, which are still immature, the "30-month curves were overlapping and crossing, a **trend that does not bode well for final [BRIGHT] results**." *See* Stephanie Hawthorne, *Not as BRIGHT as hoped: Discordant adverse events in BRIGHT versus StiL causes stir at ASH 2012*, Kantar Health Oncology Blog, http://www.kantarhealth.com (last visited May 20, 2013) (emphasis added).

190. Numerous ASH 2012 attendees rushed to the microphone to raise questions about the discrepancies between the BRIGHT and Rummel adverse event results. "Most concerning are the high rates of infection, nausea and vomiting not previously seen [in the Rummel Study] with Treanda." *Id.* The attendees were not satisfied with what they were hearing and were left "stirred up and buzzing." According to Hawthorne, "[u]ntil more follow-up (and mature PFS and OS) data is provided we will have to remain unsatisfied."

VII. CEPHALON'S USE OF KICKBACKS TO INDUCE PRESCRIBING OF TREANDA®

A. Kickbacks to CME Providers to Recommend Prescribing of Treanda® for Off-Label Use

191. In order to evade regulatory restrictions governing manufacturer-sponsored speaker programs, Cephalon has relied on CME programs facilitated by third party providers, whom Cephalon has induced to create and distribute CME programs promoting Treanda® for the front-line treatment of iNHL based on the Rummel study. Cephalon's payments to CME providers in exchange for their dissemination of an off-label promotional message controlled by Cephalon violated the Anti-Kickback Act, which prohibits the payment of remuneration in exchange for the recommendation of services payable under Government health care programs.

192. Cephalon's illicit control over CME programs to promote Treanda® for off-label, front-line use is described in greater detail in ¶¶ 133-149, *supra*. These programs were misleading because they presented the Rummel study as clear evidence of Treanda®'s superiority to R-CHOP for front-line use without disclosing what Cephalon knew to be significant flaws that undermined the Rummel study's result.

193. In one example, Cephalon exerted control over a CME program facilitated by Research to Practice titled "Hematologic Oncology Update Think Tank 2010," which as a result of Cephalon's influence recommended Treanda® for front-line treatment of iNHL. In preparation for the program, Cephalon Marketing personnel provided Research to Practice the names of three key opinion leaders ("KOLs"), who were proven advocates of off-label front-line use of Treanda®, for Research to Practice to use as speakers for the program. Cephalon also 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 and ensure favorable portrayal of Treanda® as it was being recorded. Research to Practice adhered to Cephalon's instructions and portrayed Treanda®'s effectiveness for the front-line treatment favorably as Cephalon dictated in exchange for Cephalon's payment to Research to Practice of hundreds of thousands of dollars during 2010.

194. Cephalon's payment of kickbacks to CME providers caused the providers to recommend Treanda® to oncologists for off-label front-line treatment of iNHL, which in turn caused those oncologists to prescribe Treanda® for that use and submit claims for reimbursement to Government health care programs. These claims were false because they were tainted by the underlying kickback, which rendered the claims ineligible for reimbursement.

B. Kickbacks to Paid Speakers to Prescribe and Recommend That Others Prescribe Treanda® for Off-Label Use

195. Cephalon leveraged speaker fees as kickbacks to induce speakers to prescribe Treanda® and recommend that others prescribe Treanda® for off-label front-line use. The sales force chose the topics and the speakers, who were chosen in large part based on their potential to prescribe significant quantities of Treanda®. As such, the speaker fees served as an improper effort to develop KOL product allegiance and improve the relationships between the speakers and Cephalon.

196. The Company's use of promotional speaker programs as vehicles for off-label promotion is described in greater detail in ¶¶ 150-155, *supra*.

197. The following are examples of speakers who Cephalon induced to promote Treanda® off-label for the front-line treatment of iNHL:

- Dr. Zale Bernstein, an oncologist from Buffalo, New York gave 38 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $89,650.
- Dr. David Rizzieri, a hematologist/oncologist from Durham, North Carolina gave some 39 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $200,150.
- Dr. Maureen Cooper, a hematologist from Durango, Colorado gave 18 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $119,700.
- Dr. Dan Douer, a hematologist from Los Angeles, California gave 11 Treanda® speaker programs for Cephalon in 2009 and 2010, and was paid $133,200.

198. Even after shifting the focus of its off-label promotional campaign from promotional speaker programs to CME programs by transferring $2 million from the speaker budget to Medical Affairs, 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.* 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.

199. Cephalon's payment of kickbacks to paid speakers caused the speakers to purchase and recommend that other oncologists purchase Treanda® for use in off-label front-line treatment of iNHL, which in turn caused those oncologists to prescribe Treanda® for that use. As a result, claims for reimbursement were submitted to Government health care programs. These claims were false because they were tainted by the underlying kickback, which rendered the claims ineligible for reimbursement.

C. Kickbacks Paid to GPOs to Promote Treanda® Off-Label

200. 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 used monies paid to oncology GPOs to further its fraudulent promotion of Treanda®.

201. 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").

202. 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: (i) ION, 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, owned by drug wholesaler McKesson, controls about 30% of the oncology market.

203. 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 drug makers like Cephalon the opportunity to grow off-label use if a drug is included. Not only is it in the oncologists' financial best interests to do so, since GPO members frequently receive volume-based discounts for using preferred drugs, but many oncologists also rely on these pathways for clinical advice to determine how they will treat their cancer patients, including whether and how they should prescribe drugs for off-label uses. 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. 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).

204. In order to induce GPOs to favor Treanda® for front-line treatment of iNHL and gain access to be able to promote Treanda® to physicians to whom it would otherwise not have access, Cephalon has entered into special deals with ION, US Oncology, and Onmark. This GPO "pull through" effort has been a key component of Cephalon's fraudulent promotional scheme for Treanda®. 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.

205. 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 by calling them purchases for services – e.g., data fees or disease management fees, even though Cephalon has no use for such services; or by paying excessive fees for speaker programs, which Cephalon refers to as "In-Practice Programs." That Cephalon disguised these payments to GPOs was important, because accurate characterization of the payments as rebates would have a negative impact on Treanda®'s average selling price ("ASP"), which is the key metric used to determine how much Government Programs will reimburse for each prescription.

206. 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 or inaccessible 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 promotions 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.

207. Cephalon accelerated its spending on In-Practice Programs following the release of the final Rummel study data. For example, in just the seven months following ASH 2009, Cephalon spent almost $500,000 to fund the inflated cost of these In-Practice Programs for individual US Oncology member practices in order to promote the Rummel study to them. For *each* of these programs Cephalon paid US Oncology $16,000—more than three times the cost of a traditional speaker program. The overpayment was not the result of an increased cost in conducting the programs, but was a kickback paid to US Oncology to ensure the attendance of its members. US Oncology required that for each of its member practices, at least fifty percent of its physicians *must attend* four In-Practice Programs each year. Thus, Cephalon overpays USO to promote Treanda® off-label in front of large, high prescribing oncology practices.

208. That Cephalon views these In-Practice Programs primarily as opportunities to drive off-label sales was confirmed by Cephalon Oncology's "2010 Integrated Business Plan," which included a slide entitled: "IPP: [US Oncology] Programs Yield Positive ROI." The slide demonstrates how Cephalon's investment in funding 31 US Oncology 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 12:1 "return on investment" related to the off-label message of using Treanda® to treat iNHL front-line. The slide highlights seven oncology practices that are part of the US Oncology

network and the positive impact that off-label In-Practice Programs had on their Treanda® sales growth:

- Florida Cancer Institute had 5% growth monthly from $56,520 to $59,000;
- New York Oncology/Hematology had 69% growth monthly from $76,500 to $129,150;
- Longview Cancer Center had 61% growth monthly from $13,800 to $22,200;
- Northwest Connecticut Oncology-Hematology Associates had 167% growth monthly from $15,840 to $42,300;
- Rocky Mountain Cancer Centers had 43% growth monthly from $81,360 to $116,100;
- Oncology Hematology Associates had 52% growth per month from $75,600 to $115,200; and
- Texas Oncology had growth from $0 per month to $84,150.

The increase in Treanda® sales at these clinics was the result both of Cephalon's off-label messaging during In-Practice Programs as well as kickbacks paid by Cephalon, which induced prescribing by the clinics.

209. On September 28, 2010, Jim Sterchele, Cephalon's Senior Director of Medical Affairs, circulated a promotional speaker slide deck touting the off-label use of Treanda® in the treatment of front-line iNHL. The slide deck was prepared by Cephalon's Marketing Department (i) for use in training Cephalon's paid promotional speakers, and (ii) for use by Cephalon's paid promotional speakers themselves when delivering Cephalon-sponsored presentations to physicians, including the large audiences associated with GPOs' In-Practice Programs.

210. The slide deck, entitled "TREANDA® (bendamustine HCL) for Injection: A Unique Treatment for Patients with Indolent B-cell Non-Hodgkin Lymphoma that has progressed" and internally dated August 12, 2010, provides an overview of iNHL, a general background on Treanda®, as well as a review of clinical studies involving the drug. But the on-label promotional material quickly gives way to off-label promotion of Treanda®. Specifically, the slide deck incorporates "therapeutic options" set out in the NCCN Clinical Practice Guidelines for treatment of follicular lymphoma (a form of iNHL), which recommends Treanda® plus Rituxan®, based on the Rummel data.

211. Cephalon's sales force did its part in expanding the use of In-Practice Programs as a platform to induce physicians to buy into the Company's off-label messaging about Treanda®. At a September 2010 national sales meeting in Dallas, Texas, Bob Bellucci, Cephalon's Senior Director of Strategic Accounts and Advocacy for Oncology, commended the sales representatives for their success in persuading physicians to attend Cephalon-sponsored In-Practice Programs. Bellucci made a point of presenting a slide that identified sales representatives who had done a particularly good job of recruiting physicians to attend the In-Practice Programs, and he stated that the programs would not have been successful without the sales representatives' recruiting efforts.

212. As Bellucci's statement makes clear, Cephalon handles the physician attendee recruiting, thus highlighting the fact that the excessive fees paid to GPOs for supporting In-Practice Practice programs were actually illegal inducements paid to aid the off-label promotion of Treanda®.

213. Another explicit *quid pro quo* for Cephalon's financial largesse has been to influence the favorable treatment of Treanda® on the oncology GPOs' 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."

214. 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.

D. Advisory Boards as Kickbacks to Physicians to Prescribe Treanda® for Off-Label Use

215. Cephalon's use of Advisory Boards as a forum to promote Treanda® off-label for front-line treatment of iNHL is discussed in ¶¶ 156-161, *supra*. Advisory Boards' effectiveness, however, at inducing attendees to write off-label prescriptions of Treanda® was compounded by their dual role as not only vehicles for off-label promotion, but also as kickbacks to the attendees.

216. Cephalon leveraged Advisory Boards to induce doctors to write off-label prescriptions of Treanda® for front-line treatment of iNHL through both the honoraria paid to the attendees as well as through the travel, hotels, and meals, for which Cephalon also paid. In this manner, a doctor could "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®.

217. The number of Advisory Boards that Cephalon conducted, generally multiple times per quarter, grossly exceeded what it reasonably required to obtain input from the oncology community. As such, Cephalon was not receiving legitimate services in exchange for

the fees it paid to attendees; rather, their only purpose was to induce off-label prescriptions of Treanda®.

218. Cephalon's Advisory Boards were tremendously successful at inducing the attendees to prescribe Treanda® for off-label use. Cephalon carefully monitored the "return on investment" or "ROI" of its Advisory Boards based on the increase in the quantity of Treanda® purchased by the attendees. For example, a July 22, 2010 "Treanda® Brand Review" slide deck described the "High Efficiency" of the Company's marketing tactics and stated that year-to-date Advisory Board spending of $826,000 had an ROI of 8 to 1. As such, Cephalon's inducement of physicians through Advisory Boards caused the submission to Government Programs of false, kickback-tainted claims.

E. Cephalon Offers Free Reimbursement Services As Kickbacks To Customers To Induce Off-Label Prescriptions

219. Cephalon has developed its own Medicare and Medicaid reimbursement support services for the express purpose of increasing off-label sales of Treanda®. Cephalon thereby plays a direct role in persuading Government Programs to reimburse claims for off-label, unapproved uses of Treanda®.

220. Cephalon Oncology Reimbursement ("CORE") is a program that, in Cephalon's own words, serves as "a convenient reimbursement resource that provides a support program along with online tools to help make it easier to understand the reimbursement process." In reality, CORE is a program that Cephalon has used primarily to help physicians overturn adverse Treanda® coverage decisions by payors such as Medicare and Medicaid.

221. CORE is provided free of cost to healthcare professionals, and it has been a key resource for sales representatives in their misbranding of Treanda®. Without assistance, reimbursement issues may be costly to physicians in two ways. First, in the event of a denied

claim for coverage, a medical practice must bill the patient for drugs already provided. Given the high cost of many oncology drugs, the patient may be unable to afford payment. If this cost is beyond the patient's means, the practice may then be required to assume the cost itself.

222. Second, even in the event that coverage is eventually approved, the process of obtaining that coverage can be costly for physicians and their staffs, requiring time-consuming interaction with payors. In a recent study published by the Zitter Group in September 2010, the average time required to process a typical oncology prior authorization was nearly one hour. The study further revealed that prior authorizations have a direct impact on prescribing decisions. Oncologists and practice managers reported that prior authorizations are the one payor management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Treanda®.

223. Such objections were particularly prevalent with regard to off-label uses of the drug. When prescribing drugs for on-label indications, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a drug for off-label indications, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes an off-label prescription, or a member of that physician's staff, may be required to spend considerable time interacting with the patient's insurance payor or a Government Program, arguing that the particular circumstances of the patient justify coverage of the off-label prescription. The difficulty of arguing the physician's case increases when the alternative on-label therapy is significantly cheaper than the off-label one, as has been the case with R-

CHOP and Treanda®. All else being equal, physicians are, understandably, inclined to prescribe the cheaper, on-label regimen rather than the more expensive, off-label combination in order to simplify the reimbursement process.

1. The Office of Inspector General Has Issued Advisory Opinions that Describe Problems With Free Reimbursement Support Services

224. The Office of the Inspector General for the Department of Health and Human Services ("OIG-HHS") has offered its insight on the subject of reimbursement support services, suggesting that such services are highly susceptible to fraud and abuse in Federal Programs, including Medicare and Medicaid.

225. For example, in an advisory opinion issued on October 3, 2006, the OIG responded to an inquiry regarding the propriety of a seller of durable medical equipment ("DME") offering free reimbursement consulting services to some of its customers. *See* OIG-HHS, Adv. Op. No. 06-16 (issued Oct. 3, 2006). The referenced "reimbursement consulting services" included: (1) general claims submission information, such as advice on how to code products; (2) reviewing claims; (3) helping to appeal denied claims; and (4) providing assistance related to medical justification for receiving particular products. *Id.* at 2. The OIG found that these reimbursement services constituted remuneration and that because the DME suppliers were "in a position to generate Federal health care program business" for the customers, offering such services "clearly" implicated the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b). *Id.* at 4.

226. The OIG further determined that the reimbursement consulting services at issue "would be neither limited in nature, nor free-standing," noting that the free services "would potentially confer substantial independent value upon the DME supplier." *Id.* at 5. The OIG also stated that any assistance "securing Federal reimbursement for individual beneficiaries to

receive particular products could cause beneficiaries to receive greater quantities of, or more expensive" product than they actually require. *Id.* In addition, such reimbursement services would tend to provide a financial incentive to steer customers to purchase the supplier's products, "even if products from other manufacturers were less expensive or more appropriate."

227. In this instance, Cephalon's offer of free reimbursement support services causes physicians to prescribe (and patients to receive) the more expensive treatment in the form of B-R over R-CHOP. Also, as the OIG notes, Cephalon's free CORE Program is being used as a financial incentive to persuade physicians to use Treanda® for front-line iNHL despite the fact other products from different manufacturers are "more appropriate"—i.e., evaluated and approved by the FDA. Much like the DME scenario outlined in the advisory opinion, the CORE program, as the OIG concludes, is simply a "vehicle to pay unlawful kickbacks" to Cephalon's customers in an effort to increase sales.

228. In a second advisory opinion, the OIG determined that any services, including pre-authorization services, that save a physician's office staff time, result in a realization of savings, or which were designed to refer or induce the purchase of a manufacturer's products could constitute unlawful remuneration and thus implicates the anti-kickback statute. *See* OIG-HHS, Ad. Op. No. 10-04 (issued Apr. 30, 2010). The CORE Program is specifically designed to influence prescribing and utilization decisions by making it easier and less burdensome for a physician to prescribe Treanda® off-label and ultimately obtain reimbursement from Federal Programs like Medicare and Medicaid.

2. Cephalon Uses the CORE Program To Drive Off-Label Sales of Treanda®

229. Motivated as it is by profitability, Cephalon has been required to counter oncologists' inclination to prescribe the cheaper, on-label R-CHOP treatment for front-line iNHL

instead of the more expensive, off-label B-R regimen that features Treanda®. Thus, Cephalon needed a mechanism to remove the reimbursement burden from physicians' shoulders. The CORE program accomplished this objective by supplying physicians with "front office" personnel in the form of Cephalon-contracted employees who provided free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work.

230. More specifically, with a "buy and bill" drug like Treanda®, oncologists purchase the drug directly from the drug company or a wholesaler, and thus (since they are financially on the hook if Medicare or Medicaid refuses to pay for the off-label use) they typically will prescribe Treanda® only if they know they will be fully reimbursed. Thus, to the extent obtaining reimbursement for a "buy and bill" drug that is prescribed off-label is more complicated, a physician is less likely to prescribe it. Indeed, Cephalon has acknowledged that one of the biggest obstacles to growing Treanda® sales is the lack of reimbursement for off-label uses. Cephalon increased the size of its CORE reimbursement support team to minimize this obstacle.

231. Cephalon has spent over $3 million per year (with nearly $4 million budgeted for 2011) to operate the CORE Program and provide customized reimbursement support services to doctors and their office managers, including the CORE Hotline. Cephalon has performed thousands of interventions on Medicare and Medicaid claims on behalf of healthcare providers seeking to be reimbursed for off-label Treanda® prescriptions.

232. The CORE effort has paid dividends for Cephalon. During the National Sales Meeting held in Dallas, Texas on September 20, 2010, Cephalon's Senior Director of Pricing and Reimbursement, Lisa Holmes, told attendees that the CORE program has an "overturn" rate of

82%—meaning that it is successful in reversing coverage denials 82% of the time—the majority of which are for off-label prescriptions.

233. Ms. Holmes later stated in private that Cephalon's Compliance Department had become concerned by the high overturn rate, and that the Company is considering whether it should discontinue efforts to overturn coverage denials where Treanda® was prescribed for an off-label use. Ms. Holmes' statements indicate that, regardless of what it does in the future, Cephalon has played a proactive role in assisting physicians and patients to obtain Government Program coverage for Treanda®, and in persuading Government Programs to overturn denials of coverage for off-label uses.

234. By using the CORE Program to ensure that off-label prescriptions will be reimbursed by Government Programs, Cephalon is causing the unlawful making of a false record or statement and/or causing a false claim to be submitted for the purpose of getting the false record or statement to bring about the Federal Government and *Qui Tam* States' payment of a false or fraudulent claim.

235. Cephalon's use of the CORE Program to reverse reimbursement denials for off-label prescriptions of Treanda® violates the Federal Anti-Kickback Act in that its actions have been, and are continuing to be, taken as part of a scheme to induce physicians to prescribe and utilize Treanda® for off-label uses without concern for the time, resources or lost profits associated with addressing reimbursement issues raised by payors, such as Medicare or Medicaid, themselves.

236. Cephalon's unlawful use of the CORE program to aid in the misbranding of Treanda®, and Cephalon's payment of illegal kickbacks through free reimbursement support services, involved the unlawful making of false records or statements and/or causing false claims

to be submitted for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims.

237. Cephalon, through these free reimbursement support services, knowingly and willfully offered and paid illegal remuneration in violation of the AKA, 42 U.S.C. § 1320a-7b(h)(2). But for the illegal kickbacks, Government Programs would not have paid for the off-label prescription claims tainted by these kickbacks.

F. Fall 2010—Cephalon Rewards a KOL By Purchasing Unnecessary Advertising in His Medical Journal

238. In October 2010, Dave Aspesi, Cephalon's Product Director for Treanda®, was pressured by Craig Phillips (Cephalon's Vice President of Oncology), Matt Shaulis (Cephalon's Senior Director of Oncology Marketing), and Deb Mayo (Cephalon's Senior Director of Medical and Scientific Affairs) to buy advertising in a journal called *Clinical Advancements in Hematology and Oncology*. Dr. Bruce Cheson, a KOL in the field of lymphomas and at the time an ardent supporter of Treanda®, is the Editor in Chief of that publication, and had insisted that Mayo (who oversees Cephalon's CME and publications activities) provide the funding.

239. Mayo informed VP Phillips that Dr. Cheson had called several times, making it clear that he would be greatly irritated if Cephalon did not advertise in his journal in the same amount it had the previous year. His requested amount was more than Cephalon spent on any other journal, and the Company was having difficulty justifying such a large investment in a publication that Cephalon did not consider to be well-respected. Ultimately, VP Phillips and Shaulis decided to spend the money in order to "keep Dr. Cheson happy." The purchase was a bribe to purchase his continued support as both a prescriber of Treanda® and one of its strongest proponents as a KOL in the oncology community.

240. Indeed, a quick review of Dr. Cheson's published writings in *Clinical Advancements in Hematology and Oncology* reveals his commitment to Cephalon and the Company's campaign to disseminate the off-label Rummel study data. In ten articles authored by Dr. Cheson between September 2008 and August 2010, he either provided a positive commentary on the Rummel Study, or offered an explicit endorsement of bendamustine, in combination with rituximab, for the front-line treatment of iNHL. Dr. Cheson's journal has become paid advertising for Cephalon's off-label campaign—an illegal *quid pro quo*.

241. As a result of Cephalon's purchase of advertising in his journal, Cheson has continued to prescribe and recommend that other physicians prescribe Treanda® for front-line treatment of iNHL, resulting in the submission of false claims to Government health care programs.

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

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

243. 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).

244. 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), *available at* www.nap.edu.

245. 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.

246. 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.

247. 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*, 150 Ann. Internal Med. 336 (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.

248. 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*, 150 Ann. Internal Med. 348 (March 3, 2009).

249. 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).

250. 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 Cephalon.

251. 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 M.D. 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."

252. 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 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.

253. Cephalon payment of kickbacks to NCCN has provided not only 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, but also access to one of the Compendia on which Government Programs rely to determine off-label payment. Cephalon thus has used monies paid to oncology NCCN to further its fraudulent promotion of Treanda®.

254. As such, Cephalon's inducement of physicians through NCCN caused the submission (and approval for payment) to Government Programs of false, kickback-tainted claims.

VIII. FENTORA: CEPHALON'S FRAUDULENT MARKETING CAUSED THE SUBMISSION OF FALSE CLAIMS

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

256. Actiq® was 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 per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oxycodone per day, at least 8 mg of oral hydromorphone per day, or an equianalgesic dose of another opioid for a week or longer.

257. There is no safe dose of Actiq® in patients who are not opioid tolerant. Fentanyl, the active ingredient in Actiq®, has been linked to fatal respiratory complications in non-opioid tolerant patients, and Actiq® has been associated with 127 reported deaths and another 91 reported incidents of severe adverse events.

258. 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.

259. The United States' Sentencing Memorandum and Criminal Information detailed the conduct to which Cephalon had pled guilty as follows:

- Cephalon had its sales representatives call on doctors who would not normally prescribe the defendant's drugs in the course of the doctors' practice;
- Cephalon trained its sales representatives on techniques to prompt the doctors into off-label conversations;
- Cephalon's compensation and bonus structure encouraged off-label promotion;
- Cephalon had its sales representatives tell doctors how to document their off-label uses of drugs to get these uses paid by insurers, who often will not pay for off-label uses;
- Cephalon used its grants for continuing medical education to promote off-label; and
- Cephalon sent doctors to "consultant" meetings at lavish resorts to hear the company's off-label message.

260. In order to replace the revenue stream it had enjoyed from its off-label promotion of Actiq®, which lost patent protection on September 28, 2006, Cephalon purchased a new opioid drug, Fentora®, from Cima Labs and subsequently submitted an NDA for the drug in August of 2005.

261. Fentora® was approved by the FDA on September 25, 2006 for the identical limited indication as Actiq®—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®.

262. Not only did Cephalon look to use sales from Fentora® to replace the revenues from Actiq®, it looked to target the exact set of pain specialists to whom it had illegally promoted Actiq® as its primary customer base for Fentora®, notwithstanding the fact that these pain specialists did not treat cancer patients, who are primarily treated by oncologists themselves.

263. To accomplish its goal, the Company concealed its conduct from the Government by intentionally falsifying the reports the Company was required to submit to the OIG per its CIA—a requirement that was borne from Cephalon's previous misbranding of Actiq®.

A. Background of Fentora® and Breakthrough Cancer Pain

264. 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.

265. 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.

266. 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 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).

267. 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.

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

268. 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.

269. 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.

270. 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."

271. 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.

2. The FDA Advisory Committee Concluded that Expanding Use of Fentora® To Non-Cancer Posed Unique Dangers to Patients and the Broader Community

272. On May 6, 2008, the FDA's Anesthetic and Life Support Drugs Joint Committee and Drug Safety & Risk Management Joint Committee met in a joint session (subsequently "Joint Committee" or "Committee") to discuss the risks of expanded prescribing of Fentora®, and whether those risks were great enough to preclude FDA approval of Fentora® for treatment of non-cancer breakthrough pain.

273. Advisory committees are comprised of scientific and clinical experts, as well as consumer and industry representatives, and are generally convened to provide the FDA with advice on a particularly difficult decision that requires a "value judgment" — i.e., a decision that goes beyond application of well-accepted scientific standards. In this case, the required value judgment was whether the benefits of an expanded indication would outweigh the safety risks.

274. In outlining the topics of discussion, the designated FDA official, Teresa Watkins, described the Agency's concern that in the less than two years Fentora® had been on the market: "We have already seen more reports of serious and life-threatening adverse events in both properly-prescribed and mis-prescribed patients then [sic] we have ever seen for Actiq over similar periods of time." Transcript, Joint Meeting: Anesthetic and Life Support Drugs, Joint Committee and Drug Safety and Risk Management Advisory Committee, May 6, 2008, at 17, *available at* http://www.fda.gov/ohrms/dockets/ac/cder08.html (last visited Jan. 27, 2011).

275. Watkins continued: "We at the FDA are concerned that increased prescribing might also lead to an increased level of abuse, misuse, and diversion of [Fentora®]. Due to the potency of this product, if this were to occur[,] the results may be an even more tragic public health crisis of increasing addiction, overdose, and death than we have seen with the currently

available products and indications." *Id.* at 18. "Fentora has attributes that make it particularly attractive for abuse and attributes that make it potentially dangerous for those who do abuse it." *Id.* at 20.

276. Dr. Joo Yung Chang, an FDA safety evaluator, presented post-marketing safety data for Fentora®, which included five reports of death through February 2008. "Overall, four out of five deaths involved an overdose of Fentora." *Id.* at 122. Three of these deaths were directly caused by Fentora®, two by accidental overdoses and one by suicide. The fourth death was related to, though it could not be determined that it was caused by Fentora®: a patient stole Fentora® from his wife, overdosed, was taken to the hospital and diagnosed with myocardial infarction, after which he left the hospital against advice, returned home, and died." *Id.*

277. Of the nineteen reported adverse events, only one was reported as within the FDA-approved indication, and more than half involved medication errors. *Id.* at 123-24. Lieutenant Commander Arnwine, from the FDA's Division of Medication Error Prevention, described reported medication errors in greater detail. Of the 43 reported medication errors, 35 occurred "in patients being treated for off-label use." *Id.* at 133. "One of these cases resulted in death of a patient because she took Fentora every 30 minutes for treatment of migraines." *Id.* at 135. Seven cases involved improper patient selection, including two in which patients were not on around-the-clock opioid therapy. "One of these cases resulted in respiratory depression and hospitalization...." *Id.* at 136.

278. While reported adverse events provide a useful sample of the types of adverse events that accompany use of Fentora®, reported events constitute only a small portion of actual events. Therefore, while reported adverse events provide an indication of the seriousness of the risks that accompany use of Fentora®, they do not meaningfully quantify those risks, either

absolutely or relative to other rapid-onset opioids. Multiple additional sources, however, link Fentora® not only to more serious adverse events, but also to more frequent adverse events, relative to other opioids.

279. Dr. Rob Shibuya, a Medical Officer in the Division of Anesthesia, Analgesia, and Rheumatology Products, presented evidence "that fentanyl may be more dangerous than other opioids." *Id.* at 177. In its presentation to the Joint Committee, the FDA conveyed that it regarded Fentora®'s route of administration, which facilitated ease of use and resulted in rapid onset of effect, to be a key driver of the drug's increased abuse liability.

280. Citing data from the DAWN database, Shibuya stated that fentanyl "has the highest rate of [Emergency Department] visits per 10,000 prescriptions when compared to oxycodone and hydrocodone, and this has been very consistent for the three years of data shown." *Id.* at 178. Clinical trials accentuated Dr. Shibuya's concern that Fentora® is particularly dangerous. Observations from clinical trials of Fentora® in off-label, non-cancer patients included "worrisome terms from a risk management perspective ... such as addictive behavior, physical trauma, and substance abuse, which are rarely seen in clinical trials." *Id.* at 187-88.

281. That finding was doubly troubling: not only was Fentora® linked to greater safety risks than other opioids, but those risks were greatest in non-cancer patients—the very population for which Cephalon proposed to (and even in the absence of approval, did) promote Fentora®. In two different analyses, "the events that portend risk management issues are more prevalent in the non-cancer population." *Id.* at 189. "[T]he non cancer population has an excess incidence of serious adverse events related to overdose, abuse, misuse, and those consistent with excessive CNS depression compared to analogous safety data from patients with cancer." *Id.*

282. Medical Officer Dr. Lori Love similarly emphasized that clinical trials in the non-cancer population indicate that Fentora® poses unusually large risks of abuse and misuse. Out of 931 patients, 3 percent "exhibited high risk behavior" including "abuse, dependence, overdose, and a positive drug screen." *Id.* at 148. "Seventeen percent of patients, or 156, had at least one aberrant drug use behavior," and thefts occurred in 35 patients, or 4.2% of the population. *Id.*

283. Though these figures are disconcerting in and of themselves, Dr. Love explained that they most likely *understate* the actual risks associated with Fentora® for two reasons. First, "[b]ecause this information is not available or perhaps was not gathered, the rates of abuse diversion, and aberrant behavior in general are likely unreported in these clinical trials." *Id.* at 153. Second, patients at high risk for abuse were excluded from entry to the clinical trials, meaning that those included in the trials were at low risk for substance abuse relative to the general population of would-be Fentora® users. "[T]he rates of" abuse and misuse observed in clinical trials of Fentora® in non-cancer populations "are not representative of what would occur if Fentora were approved for expanded indication in the general population with chronic pain." *Id.*

284. Dr. Love summarized: "[T]he risks of unintentional potentially fatal overdose, misuse, abuse, or diversion of fentanyl and of Fentora in particular are extremely high, as demonstrated by instances of overdose, misuse, abuse, and diversion in the clinical studies, and from signals in post-marketing data where off-label use differed from the currently[-]approved indication. These clinical trials are not representative of potential risks of Fentora in the general population. This [clinical trial] population was highly screened to eliminate high-risk patients and, further, detection of aberrant drug use is uncommon in controlled clinical trials and appears to be much more frequent in the non-cancer patients who use Fentora long term." *Id.* at 153-54.

Warning against the risks of promoting Fentora® for use in the non-cancer population, Dr. Love concluded that, "taken together, these findings suggest that expanded use of this product will raise serious public safety concerns and will result in significant abuse and diversion that further impacts the public health and safety." *Id.* at 154.

3. The FDA Advisory Committee Concluded That the Dangers of Expanded Use of Fentora® Were Greater Than the Benefits

285. Following presentations by the FDA and Cephalon, as well as a period for public comments, the Joint Committee panelists discussed whether the benefits of an expanded indication for Fentora® would justify the expected safety costs. Panelists agreed that expanded use of Fentora® would result in a significant increase in abuse, misuse, and diversion. The following comments are indicative of the Committee's discussion, and specifically of panelists' concern that Fentora®'s unique risks outweighed the modest potential benefits of an expanded indication:

- Dr. Charles Cortinovis: "And the number that would truly benefit from this very potent rapid-acting opiate would be very small, whereas we really have to consider do we want to flood the United States with this amount of product that is as potent as it is." *Id.* at 321.
- Dr. Thomas Kosten concurred that the group of appropriate non-cancer patients is "very, very small," and that the benefit to this group does not justify the expectation that Fentora® would also be prescribed to millions of inappropriate patients. *Id.* at 322.
- Dr. Frank Vocci: "But, again, the concern here is that you have a potent opioid that's now in your medicine cabinet and the diversion of this could be uniformly fatal in someone who is non-opioid-tolerant." *Id.* at 354.

- Dr. Sidney Wolfe: "And for fentanyl," the number of emergency room visits "adjusted per number of retail prescriptions," was about twice that of oxycodone and "about six times more frequent than hydrocodone and combination... And there is no question that if this were ever approved for non-cancer breakthrough pain the amount out there would be enormous. I mean, the fact that so much has gotten out there already even with it not approved is extremely worrisome...." *Id.* at 355.
- Dr. Lewis Nelson: "I'm much more concerned about putting a safe product out there, one that has tremendous public health implications, one that is particularly abusable and associated potentially with a fairly high mortality rate as well." *Id.* at 415.
- Dr. Nancy Nussmeier: "But neither of the vast majority of family practitioners or internists are chronic pain specialists in any sense of the word, so it's very scary to think that up to 30,000 physicians," which was the "core group" of physicians to whom Cephalon proposed to promote Fentora®, "would be able to prescribe the most potent, fastest-acting narcotic to up to 31 million chronic pain patients, potentially for life.... [T]hat whole scenario, going forward five or ten years, is very, very scary." *Id.* at 332.

286. By a vote of 17 to 3, Committee members concluded that the risks of abuse, misuse, and diversion outweighed the potential benefits of an expanded indication. The Committee therefore recommended that the FDA <u>not</u> approve Fentora® for treatment of non-cancer breakthrough pain.

287. 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®

288. Unburdened by the limits of the law and the rejection of its sNDA, Cephalon has 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. Cephalon has also promoted Fentora® off-label 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.

289. On March 26, 2009, Cephalon received a Warning Letter from DDMAC that 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).

290. 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*.

B. The Off-Label Promotional Scheme for Fentora®

1. The Launch of Fentora® and Off-Label Promotion Begins

291. Cephalon launched Fentora® on October 1, 2006, and its off-label promotion began that same day. Although the market for Fentora®'s only on-label treatment—BTCP—is quite limited, Cephalon's off-label promotion 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® to the pain specialists who treat a wide array of pain conditions—although BTCP is generally not among them.

292. From the first day, Cephalon used the same 100 general pain sales representatives who had previously sold Actiq® to 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 physicians who did not treat cancer patients.

293. 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*.

294. 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 (which was comprised nearly entirely by off-label use) without promoting Fentora® off-label as well.

295. 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. . . ." *See* Cephalon Q1 2007 Earnings Call, May 1, 2007, *available at*

http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript (last visited Aug. 23, 2010).

296. Roche made clear the plan was to grow Fentora® sales in pain doctors: "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." *Id.*

297. Cephalon's goal was to promote Fentora® for non-cancer breakthrough pain:

> 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. . . . 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. . 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."

Id. Roche resigned from Cephalon in January 2010 to "pursue other longstanding interests."

298. 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 misbrand Fentora® for off-label uses.

2. Off-Label Promotion of Fentora® Through Speaker Programs

299. Beginning after the Fentora® launch in 2006, Cephalon's pain sales force set up hundreds of speaker programs for healthcare professionals at which off-label promotional

presentations were offered that flouted the FDA prohibitions on such conduct. The programs were rife with illegal promotional activities. The sales force chose the topics and the speakers, who in many instances were chosen because they were also high-decile prescribers. As such, the speaker monies were an improper effort to develop KOL product allegiance and improve the relationships between the speakers and Cephalon.

300. Cephalon retained numerous physicians as Fentora® speakers who do not treat breakthrough cancer pain. For example, the Company retained numerous physical and rehabilitation medicine doctors as speakers. Physical and rehabilitation medicine physicians treat conditions such as amputation, spinal cord injury, sports injury, stroke, musculoskeletal pain syndromes such as low back pain, fibromyalgia, and traumatic brain injury. *See* Frontera, W.R., *Physical Medicine and Rehabilitation: Principles and Practice* (2010).

301. The following are examples of the speaker presentations where Cephalon's pain sales force retained physical and rehabilitation, internal medicine, pain medicine (spine), and family medicine physicians, none of whom treat breakthrough cancer pain, in order to promote Fentora® off-label:

- Dr. Srinvas Nalamachu, a physical medicine and rehabilitation specialist from Overland Park, Kansas gave some 27 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $168,700. He has also served as a consultant for Cephalon from 2005 through 2010, and principal investigator for Cephalon in studies looking at the use of Fentora® to treat non-cancer breakthrough pain. He does not treat cancer patients experiencing breakthrough pain.

- Dr. Joseph Valenza, a physical medicine and rehabilitation medicine specialist from Chester, New Jersey gave some 22 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $175,100. He does not treat breakthrough cancer pain.
- Dr. Joshua Wellington, an anesthesiologist, physical and rehabilitation specialist from Indianapolis, Indiana gave some 16 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $55,650. He does not treat breakthrough cancer pain.
- Dr. Edward Soriano, a physical medicine and rehabilitation medicine, pain medication (spine) specialist from Baltimore, Maryland gave some 7 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $59,600. He does not treat breakthrough cancer pain.
- Dr. Jeffrey Kesten, a physical medicine and rehabilitation medicine specialist from Golden, Colorado gave some 11 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $66,500. He does not treat breakthrough cancer pain.
- Dr. Louis Spagnoletti, a physical medicine and rehabilitation medicine specialist from Mariton, New Jersey gave some 8 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $30,000. He does not treat breakthrough cancer pain.
- Dr. Marc Gerber, a physical medicine and rehabilitation medicine specialist from Orlando, Florida gave some 8 Fentora® speaker programs for Cephalon

in 2009 and 2010, and was paid $24,800. He does not treat breakthrough cancer pain.

- Dr. Steven Simon, a physical medicine and rehabilitation medicine specialist from Overland Park, Kansas gave some 8 Fentora® speaker programs for Cephalon in 2009 and 2010, and was paid $44,600. He does not treat breakthrough cancer pain.

302. Cephalon uses Fentora® speaker programs to intentionally target the broader range of non-oncologists in an effort to expand the use of Fentora® beyond its lone approved indication. In fact, less than two percent of the speakers hired by Cephalon to speak on behalf of Fentora® are oncologists, despite the Company's own market research studies that show nearly 90% of oncologists diagnose and treat breakthrough cancer pain themselves and do not refer those patients to pain specialists. Further, Cephalon paid its non-oncology promotional speakers a total of $2,627,500 from the first quarter of 2009 through the second quarter of 2010, while paying its two oncologists a mere combined sum of $13,000 during that same period.

303. In November 2010, Cephalon's speaker list for Fentora® identified ninety active speakers who gave presentations on the drug. Of the ninety speakers, however, only two are oncologists. The remainder of Cephalon's paid speakers is comprised of pain specialists, psychiatrists, anesthesiologists, neurologists, rheumatologists, internal medicine physicians and primary care providers, among others. Despite Cephalon's own internal market research revealing that approximately 90% of oncologists treat their own patients suffering from BTCP (as opposed to referring them to pain specialists or other physicians), the drug maker nevertheless trains and pays healthcare providers who do not treat the on-label condition to make presentations about the drug.

304. Cephalon's decision to train and pay 88 of the 90 healthcare professionals in its Fentora® speaker bureau who are not oncologists to conduct 425 programs about the drug is a clear reflection of the Company's calculated effort to promote Fentora® for off-label uses. In contrast, between the two oncologists who are speakers for the Company (Dr. James D'Olimpio from New Hyde Park, New York and Dr. Joel Granick from Burlington, Wisconsin) who have been trained and paid to give presentations on Fentora®, only Dr. D'Olimpio gave a single oncology Fentora® program during 2009 and 2010.

3. Off-Label Promotion of Fentora® Through Journal Supplements

305. Cephalon also promoted the off-label use of Fentora® through "supplements" to medical journals. These supplements were not peer-reviewed publications but were essentially paid promotional vehicles disguised to look like medical journals, and offered Cephalon another venue to market Fentora® beyond its approved labeling. These supplements were frequently prepared in conjunction with a CME set up for Cephalon by a Medical Education and Communication Company ("MECC") to present information that appeared to be—but in reality was not—free from Cephalon's influence.

306. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)," a supplement to Anesthesiology News, Clinical Oncology News, and Pain Medicine News.

307. The supplement was prepared by McMahon Publishing, 545 West 45th Street, New York, NY 10036, and "supported" by Cephalon. Anesthesiology News is mailed monthly free of charge to all 44,832 anesthesiologists and anesthesiology residents in the United States. Clinical Oncology News is mailed monthly free of charge and/or is available in an online edition

provided to oncologists, hematologists, and oncology nurses. Pain Medicine News is mailed monthly to 50,000 of "the highest-prescribers of pain medication."

308. Although the Special Report is designed so that it appears to be objective educational material, it is blatantly promotional and is aimed simply as a marketing piece which was then distributed to well over 100,000 anesthesiologists, oncologists, and pain doctors and nurses. It contains three articles, all written by Cephalon employees, purportedly describing the new REMS procedures that were soon to be implemented by the FDA in early 2012 for Fentora® and the fentanyl class of drugs.

309. Even though the FDA's REMS for the fentanyl class of drugs specifically makes clear that these drugs are *only* to be prescribed for breakthrough cancer pain in patients who are opioid tolerant, the Special Report ignores this limitation and instead openly promotes Fentora® for non-cancer breakthrough pain. For example, in an article written by Cephalon employee Arvind Narayana, he states that "[f]entanyl buccal tablet has been shown to be effective in the treatment of BTP associated with multiple causes of pain." While he does discuss the serious risk of abuse associated with Fentora®, and thus the importance of patient selection, he then fails to note that the REMS itself and the Fentora® label limit use <u>only</u> to breakthrough cancer pain. Moreover, Narayana fails to point out to readers that the FDA had specifically rejected the Company's request to expand the label to non-cancer breakthrough pain.

310. The Special Report was also circulated by Cephalon through a free journal supplement sent out by Pharmacy Times in January 2012. Pharmacy Times has a circulation of 174,104 pharmacists throughout the United States.

4. Cephalon-Sponsored Market Research Studies Confirm Off-Label Promotion of Fentora®

311. The focus on off-label promotion of Fentora® 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® off-label to general pain specialists, instead of using its oncology sales force to promote Fentora® to oncologists, who are the physicians who treat BTCP.

312. The pressure to market Fentora® off-label was hastened, in part, by the competitive landscape for rapid onset fentanyl products. Cephalon's 2011 Fentora® Brand Plan recognized the threat of competition, noting that the market had become "extremely active," and identifying Onsolis® (Meda), Abstral® (ProStrakan) and PecFen® (Archimedes) as "3 'new' players anticipated to raise the noise of promotion in the marketplace over the next 6+ months." By expanding its promotional efforts for Fentora® to uses not approved by the FDA, Cephalon aimed to gain an advantage over the emerging competition.

313. At the Fentora FDA Advisory Committee meeting on May 6, 2008, one of the Committee members had asked Eric Floyd, Vice President of Regulatory Affairs at Cephalon, if the Company had done any market research to understand why it was that so few patients were being treated with the sole on-label use for breakthrough cancer pain. Floyd ducked the question, and asked Dr. Perry Fine to respond for the Company:

> DR. KIRSCH: I have two questions. First, one way to interpret the data to the sponsor is that you had growth and off-label use. I'm wondering if you have data, maybe survey data, from providers who care for patients with cancer pain as to why they prefer not to use this drug for breakthrough pain in their patient population?
>
> DR. FLOYD: I'll call Dr. Fine to the podium to address that.

> DR. FINE: This is Perry Fine from the University of Utah. I don't have any knowledge of any studies that have ever been done looking specifically at oncology providers or patients, specifically oncology clinics, determining, you know, what's triggering their use or non-use of Actiq and now Fentora for these cancer patients.

314. What Cephalon did not want the FDA to know was that it had in fact already completed market research survey, and in fact *knew* that its Fentora® promotions are not focused on the physicians who treat BTCP. Indeed, Cephalon had 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.

315. The first study, had been completed in 2007 (before the Advisory Committee meeting on May 6, 2008) and reported that 90 percent of oncologists diagnose and treat BTCP themselves, and do not refer their BTCP patients to pain specialists. The second study, which was completed in 2009 and prepared by Relator Cestra, 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 oncology pain is that the presence of pain can itself be an indicator of a change in the patient's underlying condition which should be monitored by the treating oncologist.)

316. Despite these overwhelming results from its own market research, Cephalon concealed this from the FDA and has continued to sell Fentora® through its general pain sales force to general pain specialists, even though it has known that it is missing approximately 90 percent of the on-label patient population.

317. Indeed, Cephalon has privately acknowledged that its initial marketing strategy for Fentora® focused almost exclusively on off-label uses. During a Brand Review meeting on December 3, 2010, which was attended by several members of senior management (including Bob Repella, Senior Vice President of U.S. Pharmaceutical Operations, and Vlad Vitoc, Senior Director of Strategic Analysis), Mr. Repella explained that Cephalon was going to expand its promotional efforts for Fentora® by calling upon approximately 2,000 oncologists for the first time. Mr. Repella explained the new policy by stating that Cephalon should be selling Fentora® in the oncology market anyway—an apparent recognition of the Company's original decision not to sell Fentora® to oncologists, and to sell it in the off-label market instead.

5. Fentora® 2011 Brand Plan Focuses on Sales for Off-Label Non-Cancer Breakthrough Pain

318. Cephalon's strategy to focus its promotion of Fentora® on general pain specialists who do not treat Fentora®'s on-label indication of BTCP was confirmed in Cephalon's "Fentora® Brand Plan 2011," an internal Company document that sets forth sales and marketing goals for the drug. The "FENTORA 2011 Brand Plan," outlines Cephalon's strategy and tactics for promoting Fentora® during 2011 and beyond. Because the plan was intended for wide distribution within Cephalon's management, it reflects a clear effort to sterilize the documents of references to the Company's off-label promotional scheme; however, the document still provides strong evidence of Cephalon's off-label promotional scheme for Fentora®.

319. Despite paying a significant settlement as a result of its off-label promotion Actiq® and entering a Corporate Integrity Agreement designed to prevent continued off-label promotion, the "FENTORA 2011 Brand Plan" clearly reflects that Cephalon has built on its off-label promotion of Actiq® as the basis for its promotion of Fentora®. Cephalon sought to convert pain specialists, who prescribed Actiq® off-label as a result of the Company's former off-label

promotional effort for Actiq®, to instead prescribe Fentora® off-label for those same off-label uses. In summarizing its previously established objectives for 2010, Cephalon's first-listed objective was to "minimize prescriber losses / re-activate former prescribers." Given that the vast majority of prescribers of both Actiq® and Fentora® were pain specialists who did not prescribe Actiq® for its on-label use, the Company's goal is to maintain market share among these off-label prescribers. The Brand Plan signals that, for 2010, that objective was successfully met, with "a positive trend and stabilization in the FENTORA business."

320. Moving forward into 2011, the Company planned to pursue a similar strategy of leveraging relationships with pain specialists to drive sales of Fentora®, despite the knowledge that pain specialists do not prescribe Fentora® for its on-label use. Facing ever-increasing competition from other fentanyl-based drugs such as Onsolis®, Abstral®, and PecFen®, Cephalon conducted a competitive strategy workshop in order to determine how to best differentiate Fentora® from these competing drugs. Among the three "key areas" identified by the workshop to differentiate Fentora® were "existing relationships with pain community," yet again emphasizing the centrality of this primarily off-label demographic in Cephalon's promotional strategy for Fentora®.

321. The Fentora® Brand Plan, in fact, contains repeated references to the continued centrality of pain specialists in Cephalon's promotional strategy for Fentora®. Oncologists, the physicians who constitute 90% of the on-label market for Fentora®, are almost always listed as secondary promotional targets. A "Tactical Plan" included in the Brand Plan lists fourteen "Tactic[s] & Objective[s]" as well as the corresponding target audiences for each tactic. For ten of the fourteen tactics and objectives, pain specialists are the first-listed target. Only for *two* of

the fourteen are oncologists listed first. This list is indicative of the prominence of pain specialists in the Company's promotional scheme.

322. Likewise, Cephalon targets speakers, advocates, and consultants who are primarily from the pain management field, rather than from the oncology field. The "Pain Knowledge Mapping Project" is a project specifically designed to "identify and profile prominent experts in the field of pain management," and an "[e]ditorial board" of "[t]op-tier advisors" is to be composed entirely of "5-6 pain specialists." These pain specialists would serve to facilitate Cephalon's broader targeting of pain specialists by "advis[ing] the marketing team on marketing projects, initiatives, messages."

323. While the Fentora® Brand Plan also contains objectives to increase promotions to oncologists, these objectives serve to emphasize the very limited extent to which Cephalon has targeted oncologists in the past. The "Advisory Board Plan of Action" lists as a focus, "Engage oncology experts," elaborating that "[m]ore needs to be done to gain feedback from oncologists and oncology nurses as we continue to expand our commercial presence with these important groups."

324. More importantly though, these efforts to expand promotion to oncologists remain secondary to Cephalon's efforts to expand and continue promotion to pain specialists. The Fentora® Brand Plan includes a goal of broadening the targeted audience beyond the current group of 1,800 healthcare professionals ("HCPs") to include an additional 750 rapid-onset-opioid-("ROO-") prescribing oncologists and another 1,235 non-ROO-prescribing oncologists. While that indeed constitutes a significant expansion in the Company's promotion to oncologists, that expansion is nonetheless dwarfed by Cephalon's promotional expansion to 5,500 other

ROO-prescribing HCPs. That is, oncologists constitute barely more than one-fourth of Cephalon's expanded target audience.

325. According to the Fentora® Brand Plan itself, Cephalon's off-label promotion of Fentora® has been successful. The Brand Plan states that "[r]epresentative driven detailing activities . . . have demonstrated a significant impact[,] driving 29% of FENTORA sales historically." Given that only 7% of total Fentora® prescriptions were written by oncologists, and that these 7% almost entirely constituted the on-label market for the drug, this statement is a surprisingly explicit admission that Cephalon's sales representatives have been instrumental at driving off-label market share for Fentora®.

326. In fact, that 29% figure likely understates the significance of sales representatives' effect on prescriptions of Fentora®, as the Brand Plan attributes the remaining 71% of Fentora® sales to "carryover as a result of physician loyalty and past promotion," namely the Company's former off-label promotion of Actiq®.

327. In apparent recognition of the significant impact of its sales representatives' continued promotion of Fentora® to pain specialists, Cephalon planned to allocate even more resources to targeting pain specialists. The Brand Plan recommends that for 2011 Cephalon "[i]ncrease/reallocate marketing spend based on historical responsiveness of physician segment," recognizing that "there is an opportunity to refine the allocation of key sales force activities to optimize that return on investment."

328. The Fentora® Brand Plan is circumspect about the details of this reallocation; however, the "AMRIX 2011 Brand Plan" provides clarification. Amrix® is a skeletal muscle relaxant that is used to prevent painful skeletal muscle spasms. Cephalon promotes Amrix®

through Pain Specialist Sales People ("PCS"), who are also responsible for promoting Fentora®. "The PCS team primarily covers pain specialists. . . ."

329. While the PCS team formerly devoted 70% of its resources to promoting Amrix® and 30% to promoting Fentora®, this allocation left "FENTORA under-resourced . . . based on ROI and brand potential." Thus, in January 2011, the team swapped its resource allocation, devoting 70% of its resources to promoting Fentora® and only 30% to Amrix®. In effect, Cephalon increased its devotion of resources to promote Fentora® to pain specialists, necessarily implying that the increase is largely dedicated to promoting Fentora® off-label.

C. Cephalon Offers Kickbacks To Customers To Induce Off-Label Prescriptions of Fentora®

330. Similar to its effort with the CORE Program for Treanda®, Cephalon has developed and manipulated its own Medicare and Medicaid reimbursement support service for the express purpose of increasing off-label sales of Fentora®. Through its Fentora Reimbursement Program, Cephalon plays a direct role in persuading Government Programs to reimburse claims for off-label, unapproved uses of Fentora®.

1. The Fentora® Reimbursement Program and the High Cost of Obtaining Reimbursement

331. The Fentora® Reimbursement Program is a program that, in Cephalon's own words, "provides tools and services that may facilitate the reimbursement process." According to Cephalon's website, the Fentora® Reimbursement Program is designed to help patients and physicians with pre-authorizations and denied claims. In reality, however, the Fentora® Reimbursement Program is a program that Cephalon has used primarily to help physicians overturn adverse Fentora® coverage decisions by payors such as Medicare and Medicaid.

332. The Fentora® Reimbursement Program is provided free of cost to healthcare professionals, and it has been a key resource for sales representatives in their off-label promotion of Fentora®. Without assistance, reimbursement issues may be costly to physicians. Even assuming that coverage is eventually approved, the process of obtaining that coverage can require time-consuming interaction with payors.

333. In a recent study published by the Zitter Group in September 2010, the average time required to process a typical oncology prior authorization was nearly one hour. The study further revealed that prior authorizations have a direct impact on prescribing decisions. Oncologists and practice managers reported that prior authorizations are the one payor management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Fentora®.

334. Such objections are particularly prevalent with regard to off-label uses of the drug. When prescribing drugs for on-label indications, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a drug for off-label uses, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes an off-label prescription, or a member of that physician's staff, may be required to spend considerable time interacting with the patient's insurance payor or a Government Program, arguing that the particular circumstances of the patient justify coverage of the off-label prescription. The difficulty of arguing the physician's case increases when the alternative on-label therapy is significantly cheaper than the off-label one. All else being equal, physicians are,

understandably, inclined to prescribe the on-label option rather than the off-label one in order to simplify the reimbursement process.

2. Cephalon Uses the Fentora® Reimbursement Program To Drive Off-Label Sales

335. Cephalon has been required to counter physicians' inclination not to prescribe a powerful opioid for the treatment of off-label, non-cancer breakthrough pain. Thus, Cephalon needed a mechanism to remove the reimbursement burden from physicians' shoulders. The Fentora® Reimbursement Program has accomplished this objective.

336. Cephalon has acknowledged that one of the biggest obstacles to growing Fentora® sales is the lack of reimbursement for off-label uses. Cephalon increased the size of its reimbursement support team to minimize this obstacle. Cephalon spent over $3 million per year (with nearly $4 million budgeted for 2011) to provide customized reimbursement support services to doctors and their office managers, including a Fentora® Hotline. Cephalon has performed numerous interventions on behalf of healthcare providers seeking to be reimbursed for off-label Fentora® prescriptions.

337. In April 2011, Lisa Holmes, Senior Director of Pricing and Reimbursement, met with Cephalon's Compliance Department—at the request of Compliance. The purpose of the meeting was to discuss the resources Cephalon supplies physicians and office managers handling reimbursement issues, specifically those relating to the appeal and overturn denials for coverage of Treanda® for off-label uses. Internally, there was also a concern about Cephalon's role in the reversal of reimbursement denials for Fentora®.

338. Cephalon's role in the reimbursement support service, which has been offered to physicians since at least March 2008, is well-defined. First, when a physician or physician's office contacts Cephalon's hotline for reimbursement support to overturn a denial for off-label

uses, the Company has a pre-populated form with all relevant off-label data and studies it has identified as supporting the use and reimbursement of Treanda® or Fentora® for those uses. The pre-populated form allows the physician or their staff to only fill in the patient-specific information and send it to the payor, requesting that the payor reimburse for such off-label use of Treanda® or Fentora®. Importantly, Cephalon has generated a pre-populated form for most off-label disease states, including non-cancer breakthrough pain, to push through authorizations for off-label reimbursement.

339. Cephalon's unlawful use of the Fentora® Reimbursement Program in the off-label promotion of Fentora®, and its payment of illegal kickbacks through free reimbursement support services, involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims. Cephalon, through these free reimbursement support services, knowingly and willfully offered and paid illegal remuneration in violation of the AKA, 42 U.S.C. § 1320a-7b(h)(2).

340. But for the illegal kickbacks, Government Programs would not have paid for these false claims for off-label uses. The Company's actions were taken as part of a scheme to induce physicians to prescribe and utilize Fentora® for off-label uses without concern for the time, resources or lost profits associated with addressing reimbursement issues raised by payors, such as Medicare or Medicaid, themselves.

IX. CEPHALON VIOLATED THE CORPORATE INTEGRITY AGREEMENT BY INTENTIONALLY FALSIFYING OR CONCEALING ITS ILLEGAL CONDUCT IN REPORTS SUBMITTED TO THE GOVERNMENT IN ORDER TO OBTAIN ILLEGAL REIMBURSEMENT

341. In order to execute its off-label promotion and kickback scheme for Treanda® and Fentora®, the Company needed to conceal its illegal conduct from Government oversight,

particularly in light of the fact that it was operating under a Corporate Integrity Agreement ("CIA" or "Agreement").

342. Accordingly, Cephalon engaged in a deliberate plan to knowingly submit false reports to the OIG—as required per the terms of the CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether. As such, Cephalon knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

A. The Corporate Integrity Agreement Establishes Cephalon's Monitoring and Reporting Obligations

343. As part of the September 2008 Settlement Agreement with the Federal Government and various *Qui Tam* States, 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 promotion or payment of kickbacks.

344. The Agreement states that Cephalon "hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements)."

345. The CIA is an express contract between Cephalon, the U.S. Department of Health and Human Services and the United States Government.

346. All of Cephalon's employees were aware of the CIA, as the CIA required a written Code of Conduct be distributed to all Covered Persons, and each Covered Person was required to certify, in writing, that he or she had received, read, understood, and would abide by Cephalon's Code of Conduct. CIA pg. 7, III.B.1 (defining "Code of Conduct"). Pursuant to the CIA, the Code of Conduct was to specify that all Covered Persons shall be expected to comply with the requirements of the CIA. *Id.* Per the CIA, a "Covered Person" includes officers, directors, and United States-based employees of Cephalon. CIA, pg. 2, II.C.1.a.

347. The CIA contains an express contractual agreement that all Cephalon employees "shall be expected to report to the Chief Compliance Officer, or other individual designated by Cephalon, suspected violations of any Federal health care program and FDA requirements or of Cephalon's own Policies and Procedures."

348. 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 has intentionally ignored that requirement.

349. The CIA also 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).

350. From the day Cephalon signed the CIA and announced, "We 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.

351. Cephalon, through its Compliance Department, (1) falsely certified in its quarterly reports that the company had fully complied with its CIA obligations; (2) manipulated off-label data obtained via third-party audits to minimize the true extent of the Company's off-label promotion; and (3) concealed from the Government reportable events that were brought to the Company's attention by employees who were fulfilling their obligation to report violations of federal and state laws.

352. 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.

B. Cephalon Continues Its Illegal Conduct Even While Negotiating the Terms of Its Corporate Integrity Agreement

353. Cephalon had entered into an agreement in principal with the Government in September 2007, and finalized the Settlement Agreement on or about September 29, 2008. The Company signed its Corporate Integrity Agreement on September 26, 2008. Even after entering into the agreement in principle with the United States in 2007 and signing the Settlement Agreement and CIA in 2008, however, Cephalon continued its off-label promotion and payment of kickbacks as if neither event had occurred.

C. Internal Audits Reveal Cephalon's Off-Label Promotion of Treanda®

354. As part of its Settlement Agreement, 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.

355. In 2010 and 2011, Cephalon conducted several 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.

356. The audits capture the precise off-label messaging that Cephalon's sales representatives were using to promote Treanda® off-label to physicians. The spreadsheets used to catalogue the audit results include columns with the heading "Off-Label Topic the Sales Representative Specifically Discussed." The following verbatim responses, reported by the audited physicians during the first quarter of 2011, provide a sampling of how the Company's off-label scheme was actually carried out by its sales representatives:

- "use of frontlien (sic) rx in patients with low grade lymphomas";
- "Combination treatment with Rituximab for NHL patients"; and
- "use with Rituxan in first line."

357. Another column within the audit spreadsheet, entitled "Main Message of the Presentation," also provides insight into the depth and nature of Cephalon's off-label promotion to physicians. Importantly, the off-label verbatims listed below do not reflect any discussions on subjects that were initiated by the physicians. These examples include:

- "study showing r chop vs treanda rituxan with comparable efficacy and less toxicity and tolerability";
- "Minly (sic) discussed trial data comparing rituxan-treanda to rituxan -chop in follicular NHL";
- "We discussed the Rummell (sic) data detailing the use of BR as first line treatment for low grade FL";
- "efficacy of treanda with rituxan in . . . nhl";
- "You can take it any line of therapy in any combination";
- "German trial comparing R-CHOP vs BR";
- "again use in cll and non hodgkins lymphoma. discussed how the community uses it with rituxan";
- "as effective as r chop in indolent nhl";
- "br as the first line low grade"; and
- "use . . . upfront tx for follicular NHL."

358. The audit results show that the scheme devised by Cephalon's senior management successfully reached its targeted physician audience through the Company's sales force.

D. Cephalon Manipulated Internal Audits Showing Off-Label Promotion of Treanda® and Thus Made False and Misleading Statements In Its Reports To the OIG

359. 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 the Company's being under a CIA, the compliance issues he raised should *already* have been a thing of the past.

360. Cephalon made an effort to make it appear that it did not condone off-label promotion by cutting sales representatives' bonuses by 25%. However, the bonus reduction was 'smoke and mirrors' and 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 stood to lose per quarter was $3,250. Sales representatives have recognized that it is in their financial interests to continue promoting Treanda® and Fentora® off-label, even with the small bonus deduction because they can earn substantially more by promoting the drugs off-label than if they only sold only for on-label uses.

361. Indeed, during a 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® and Fentora® off-label were 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 off-label promotional scheme.

362. On September 20, 2010, during a national sales meeting in Dallas, Craig Phillips, then Cephalon's Vice President for the Oncology Business Unit (and attended by Relator Cestra), made a presentation to the Company's oncology sales representatives and executives.

VP Phillips reported that, according to Cephalon's most recent audit of its sales force's off-label messages, required by the Corporate Integrity Agreement, only 5.5% of sales calls during the third quarter of 2010 included off-label discussions, representing a decline from 15% in the first quarter of 2010. VP Phillips also reported to the sales force that the total number of oncology sales calls (whether on- or off-label) had dropped by 25 percent (from 4,000 per month to 3,000 per month) during the same period, translating to fewer than two physician sales calls per sales representative per day during the third quarter. These numbers were calculated based on information provided by the sales representatives themselves, who are required to log their sales calls into Cephalon's call tracking computer system.

363. VP Phillips told those present that Cephalon's Executive Committee and Compliance Department believed the supposed decrease in both on- and off-label sales calls did not reflect reality. Instead, this reflected management's belief that sales representatives had stopped logging off-label sales calls after learning that the calls were being audited pursuant to the existing Corporate Integrity Agreement. It was apparent that the sales force was circumventing the system put in place to audit off-label misbranding activity in order to avoid being identified in a subsequent internal audit. By not properly accounting for the Treanda® sales calls that were actually made on physicians, Cephalon was intentionally concealing and minimizing the extent to which these calls involved off-label promotion.

364. After manipulating the manner in which the data was collected, the Company then actively falsified how the already-suspect results would be reported to the Government.

365. More specifically, when the Compliance Department received the results from the auditor, the Company set up meetings with the sales and marketing personnel (including Relator Cestra) to go over the findings. With regard to the figures involving the promotion of Treanda®,

Karen Lowney reviewed the data with Dave Aspesi, the Product Director. Upon reviewing the information, Aspesi noted that the audit report showed physicians reporting multiple statements made by sales representatives that reflected unsubstantiated superiority and safety messages regarding Treanda® that were not in the drug's FDA-approved label. For example, the audit showed instances in which Cephalon representatives promoted Treanda® as being safer or having better tolerability than fludarabine, a claim not in the product label.

366. Aspesi then pointed out that these statements were off-label because they were not supported by any head-to-head clinical studies comparing the treatments. When he raised these issues, Lowney declined to classify those claims (and others) as reportable off-label events under the CIA. Aspesi impressed upon Lowney that the manipulated audit results artificially decreased the off-label figures. He added that the inaccurate data, which was to be included in the reports sent to the Government as part of the CIA, created a false account of the actual off-label promotional activity at Cephalon. However, Lowney ignored Aspesi's concerns, stating that Cephalon was only concerned with reporting to the OIG claims regarding efficacy. Lowney explained that it was the Company's interpretation of the CIA that did not have to report any off-label safety claims—even unsubstantiated comparative claims. That is, Cephalon categorically refused to report to the OIG these untrue and misleading safety claims.

367. When Cephalon intentionally manipulated and falsified the data regarding off-label promotion, it violated the terms of the CIA.

E. Cephalon Violated Its Corporate Integrity Agreement By Not Reporting to the Government the Use of the Off-Label Promotional Slide Deck

368. In early 2011, Cephalon's Compliance Department was made aware of the off-label portion of the promotional slide deck that highlighted the NCCN Guidelines' support for Treanda® in the front-line treatment of iNHL. The presentation material at issue had been used

in the field for a number of months. Further, the promotional material, which had been approved by the Company, had been used extensively in the company's In-Practice Programs.

369. A meeting was held to discuss the compliance issue (at which Relator Cestra attended). The meeting was attended by, among others, Carol Marchione (Senior Director of Regulatory Affairs), David Aspesi, (the Treanda® Marketing Director) and Bryan Stefansky (Associate Director of Compliance). During the meeting, Marchione insisted that she was heavily pressured into approving this slide and that she had not wanted to include that particular material in the presentation. Marchione did not indicate who was responsible for pressuring her. Ultimately, even though the slide deck was blatantly off-label, the Compliance Department declined to follow up with Marchione or investigate the matter further.

370. Notwithstanding Cephalon's decision to ignore the compliance reporting, the documented use of the off-label information in Cephalon's promotional material constituted a reportable event per the CIA. Pursuant to the terms of the CIA, Cephalon is required within 30 days after discovery to notify the HHS-OIG in writing of any "reportable event," which is defined as:

> anything that involves . . . a 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.

See Cephalon Corporate Integrity Agreement, at III.H.

371. The CIA also requires that Cephalon provide the OIG with a copy of the report, as well as written notice of any resolution of such disclosed off-label matter within 30 days, including a description of any finding or results. *See id.* III.I.

372. Plainly, Cephalon's use of the NCCN guidelines to promote Treanda® off-label is a reportable event as defined by the CIA. Further, Cephalon's decision to not notify the Government about the incident—irrespective of any conclusions the Company may have drawn about complaint—violated its obligation under the CIA to self-report instances of off-label promotion.

F. Cephalon Concealed Its Off-Label Promotion of Fentora® and Thus Made False and Misleading Statements In Its Reports To the OIG

373. Cephalon's promotion of Fentora® for off-label uses constiuted a violation of the Company's CIA and, when considered together with its illegal promotion of Treanda®, is a remarkable admission that the Company does not take seriously its obligations under the prior plea agreement.

374. Cephalon violated the terms of the CIA each time it failed to properly report to OIG the promotion of Fentora® to physicians who the Company knew did not treat BTCP. Cephalon's active concealment of these illegal activities furthered its Fraudulent Marketing Scheme.

G. Cephalon Violated Its Corporate Integrity Agreement By Not Reporting to the Government the Illegal Kickbacks It Paid To Physicians and GPOs

375. Similar to its failure to report off-label promotional activities to OIG, Cephalon likewise violated the terms of the CIA by not including in its reports the illegal kickbacks that it paid to induce physicians to prescribing Treanda® and Fentora®.

376. The Federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), is specifically cited in the CIA and otherwise referenced as a law "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."

377. Cephalon violated the express terms of the CIA each time it failed to properly report to OIG the financial inducements the Company paid to GPOs, the free reimbursement services it provided to physicians and the payments made to KOLs for unnecessary advertising in their publications. Cephalon's active concealment of these illegal activities furthered its off-label promotional scheme.

X. THE FRAUDULENT MARKETING SCHEMES CAUSED THE SUBMISSION OF FALSE CLAIMS TO FEDERAL AND STATE HEALTH CARE PROGRAMS

378. Cephalon's off-label promotional 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.

379. 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, unjustly enriching Cephalon.

A. Cephalon's Payment of Kickbacks Caused the Submission of False Claims and Making of Material False Statements to Government Programs

380. Cephalon provided health care professionals, contractors, and publishers with remuneration related to CME programs, promotional speaker programs, In-Practice Programs, Advisory Boards, reimbursement services, and compendia recommendations, all in return for or to induce purchasing, ordering, arranging for or recommending purchasing or ordering of goods or items for which payment was made by Government Programs, in violation of the federal Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), and state analogues. *See* ¶¶ 191-254, 330-340, *supra*.

381. These kickbacks caused health care professionals to prescribe or recommend that other healthcare professionals prescribe Cephalon's drugs.

382. As described in detail in ¶¶ 402-421, *infra*, these actions in turn caused physicians (in the case of Treanda®) and pharmacists (in the case of Fentora®) to submit claims for reimbursement for Cephalon's drugs to Government Programs, including Medicare and Medicaid.

383. Government Programs, including Medicare and Medicaid, do not cover claims for drugs where there is a kickback involved in the underlying transaction—including claims that were submitted for payment of a drug as a result of a kickback given to a health care professional to prescribe that drug. Claims submitted to Government Programs where a kickback is involved in the underlying transaction are false within the meaning of the federal False Claims Act and State analogues.

384. In order to enroll in and bill Medicare, providers must sign CMS Form 855, which states:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

385. Similarly, any provider who submits claims to Medicaid must sign a provider agreement with each Medicaid program to which it submits claims. Massachusetts regulations, for example, provide that: "All pharmacies participating in MassHealth must comply with the regulations set forth in 130 CMR 406.000 and 450.000." The Massachusetts regulation at 130 CMR 450.261 provides: "All members and providers must comply with all federal and state laws

and regulations prohibiting fraudulent acts and false reporting, specifically including but not limited to 42 U.S.C 1320a-7b," the federal Anti-Kickback statute.

386. Claims that were submitted to Government Programs as a result, in part or in whole, tainted by kickbacks provided by Cephalon were therefore false within the meaning of the federal False Claims Act and State analogues.

387. Cephalon's payment of kickbacks therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

388. Cephalon's payment and offers of payment of kickbacks were made knowingly and with the intent to cause the submission of false claims to Government Programs.

389. Government Programs paid reimbursements for those false claims, and as a result have incurred and continue to incur significant damages due to Cephalon's illegal payment of kickbacks.

390. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Cephalon also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 402-421, *infra*.

B. Cephalon's Off-Label Promotion Caused the Submission of False Claims and Making of Material False Statements to Government Programs

391. In order for a drug to be eligible for reimbursement by Medicare Part D, it must be, in relevant part, approved by the FDA and used for a "medically accepted indication." 42 U.S.C. § 1395w-102(d)(1) & (e)(4)(A)(ii). A medically accepted indication is defined as any use which is FDA-approved or which is supported by one or more citations included or approved for inclusion in one of three specified drug Compendia. Specific coverage policies and decisions are

generally made by sponsors who contract with CMS to provide such coverage and are responsible for making coverage determinations in accordance with statutes and regulations.

392. In order for a drug to be eligible for reimbursement under the Medicaid program, the drug's manufacturer must first enter into a rebate agreement with HHS. Once a manufacturer has entered into a drug rebate agreement a state is generally required to cover the covered outpatient drugs of that manufacturer under the state plan unless "the prescribed used is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). A medically accepted indication is any FDA-approved use or a use that is "supported by one or more citations included or approved for inclusion in any of the Compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6). Thus, Medicaid ordinarily does not cover off-label uses of drugs that are not supported by one or more citations included or approved for inclusion in the specified Compendia.

393. Other Government Programs adhere to similar rules in determining a drug's eligibility for reimbursement and generally require that in order to be covered a drug must be prescribed for an FDA-approved use or a use supported in one or more drug Compendia.

394. Cephalon promoted Treanda® and Fentora® for uses that were neither approved by the FDA nor supported in any one of the applicable drug Compendia, and as a result were ineligible for reimbursement by Government Programs including Medicare and Medicaid.

395. As a result of Cephalon's off-label promotion of its drugs, physicians prescribed Cephalon's drugs for these uses.

396. As a result of physicians' prescribing of Cephalon's drugs, physicians (in the case of Treanda®) and pharmacists (in the case of Fentora®) filled prescriptions and submitted claims to Government Programs for payment of Cephalon's drugs for these uses, as described in detail in ¶¶ 402-421, *infra*.

397. Because claims for payment of Cephalon's drugs were ineligible for reimbursement by Government Programs, these claims were false within the meaning the federal False Claims Act and State analogues.

398. Cephalon's off-label promotion of Treanda® and Fentora® therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

399. Cephalon engaged in this off-label promotion knowingly and with the intent to cause the submission of false claims to Government Programs.

400. Government Programs paid reimbursements for the resulting false claims, and as a result have incurred and continue to incur significant damages due to Cephalon's off-label promotion of its drugs.

401. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Cephalon also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 402-421, *infra*.

1. Submission of False Claims to Medicaid

402. The physicians' offices and pharmacies where Cephalon's drugs are filled agree to provide pharmaceuticals to the patients served by the *Qui Tam* States' Medicaid programs, and the *Qui Tam* States in turn reimburse these office and pharmacies for the cost of the Cephalon drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicaid patients.

403. The offices and pharmacies submit their Medicaid claims for reimbursement by "batching them" daily, and submitting them electronically to the Qui Tam States. These claims

include the claims for off-label prescriptions for the Cephalon drugs, as well as claims tainted by illegal kickbacks. In instances in which claims were for off-label prescriptions or tainted by illegal kickbacks, the office and pharmacies make false representations and false claims concerning Medicaid reimbursement directly to the *Qui Tam* States on a daily basis.

404. As part of each electronic claim, the office and pharmacies affix their unique Medicaid provider identification numbers, which serve as electronic stamps indicating that (as Medicaid providers) they are in compliance with all applicable federal and state laws.

405. The offices and pharmacies are reimbursed on a monthly basis by the *Qui Tam* States for all approved claims.

406. The *Qui Tam* States are not financially responsible for paying 100% of the offices and pharmacies' claims for reimbursement. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups, primarily low-income and disabled persons. The federal Government provides matching funds and ensures that the states comply with minimum standards in the administration of the program. The federal share of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on each individual state's per capita income compared to the national average. Among the states, the FMAP is at least 50%, and in some instances, as high as 77%. For example, for fiscal year 2004, in Virginia, Massachusetts and Illinois, the federal share was 50%. *See Federal Medical Assistance Percentages or Federal Financial Participation in State Assistance Expenditures FMAP*, Office of the Assistance Secretary for Planning and Evaluation, http://aspe.hhs.gov/health/fmap.htm (last visited Mar. 29, 2011).

407. Through the FMAP process, State Medicaid administrators obtain the Federal Government's share of the pharmacies' reimbursements by submitting a quarterly Form 64 to

CMS. For this reason, claims submitted to state Medicaid agencies, including those in the *Qui Tam* States, are presented to the Federal Government within the meaning of the FCA.

408. The Federal Government pays Medicaid claims through a continuing line of credit certified by the Secretary of the Treasury in favor of the state payee. 42 C.F.R. § 430.30(d)(3), (4). The Federal Government authorizes the state payee "to draw Federal funds as needed to pay the Federal share of disbursements." 42 C.F.R. § 430.30(d)(3). The state can draw down on those funds only to pay the Medicaid claims of healthcare providers. 42 C.F.R. § 430.30(d).

409. The funds made available to the state thus remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay the offices or pharmacies' claims.

410. The Federal Government also "approves" within the meaning of the FCA the claims submitted and paid through the Medicaid program. When a state presents its Form 64 (i.e., the quarterly report of actual expenditures) to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter.

411. Because the Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstated the amount of federal funds to which the state was entitled by the amount fraudulently paid as a result of off-label prescriptions for the Cephalon drugs, as well as claims tainted by illegal kickbacks. They

were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States.

412. The claims for reimbursement submitted by the physicians' offices and pharmacies to the *Qui Tam* States, which in turn caused the *Qui Tam* States to submit these claims for reimbursement to the Federal Government pursuant to FMAP, constituted false claims as a result of the claims for reimbursement for off-label prescriptions and claims tainted by illegal kickbacks.

2. Submission of False Claims to Medicare Part B

413. When administered on an outpatient basis, injectable and infusible oncology drugs, including Treanda®, are reimbursed under Medicare Part B. When providing chemotherapy as a service under Part B Medicare, physicians purchase the drugs, manage inventory, administer drugs in-office, and submit claims to Medicare and Medigap insurers for reimbursement of the drugs and certain associated administrative costs, such as copay collections. This process is commonly referred to as "buy and bill."

414. A physician who administer chemotherapy drugs to Medicare beneficiaries submits claims for both the drug and its administration to obtain reimbursement from the Medicare Part B program. Reimbursement for Medicare claims is made by the United States through CMS, which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS. The physician submits to the carrier a standard paper or electronic claim form (typically on Form CMS-1500) that contains information about the services performed and drug product administered to the patient. The carrier then passes the claim through a series of automated edits, calculates the correct reimbursement for the claim, and issues payment to the physician.

415. When a physician submits a claim for payment, the claim is subject to and under the terms of certifications made to the United States that the services for which payment is sought were delivered in accordance with federal law, including without limitation the Anti-Kickback Statute.

416. Defendants knew that their conduct caused physicians (and other health care providers) to submit Treanda claims that were non-covered, or otherwise ineligible for reimbursement, but billed as if they were covered, and caused physicians to falsely certify their compliance (including pursuant to Form CMS-855) as Medicare providers.

417. Claims submitted by physicians and other health care providers to Medicare carriers for non-reimbursable off-label uses and as a result of receipt of kickbacks constituted false claims.

3. Submission of False Claims to Medicare Part D

418. The pharmacies where the Cephalon drugs are filled agree to provide pharmaceuticals to Medicare Part D Plans ("PDPs") for Medicare patients that they serve, and the PDPs in turn reimburse these pharmacies for the cost of the Cephalon drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicare patients. PDPs (or MA-PDPs) are administered under contract with CMS by private entities such as Blue Cross Blue Shield plans, large commercial insurers such as Humana, and pharmacy benefit managers.

419. Every time a beneficiary fills a prescription covered under Part D, PDPs must submit a summary called the prescription drug event, or PDE record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. CMS uses the

PDE record to calculate reimbursement to PDPs for the cost of the Cephalon drugs, plus an amount meant to provide the PDPs with a profit for administering the PDP.

420. CMS reimbursement to PDPs pursuant to the PDE overstated the amount of federal funds to which PDPs were entitled by the amount fraudulently paid as a result of off-label prescriptions for the Cephalon drugs, as well as claims tainted by illegal kickbacks. They were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States.

421. The claims for reimbursement submitted by the pharmacies to PDPs, which in turn caused the PDPs to submit these claims for reimbursement to the Federal Government, constituted false claims as a result of the claims for reimbursement for off-label prescriptions and claims tainted by illegal kickbacks.

XI. CEPHALON'S RETALIATION AGAINST RELATOR

422. On two separate occasions, Cephalon illegally retaliated against Relator in response to his having come forward to report the Company's illegal promotional activities and kickback schemes for internal investigation.

423. First, soon after reporting his concerns to Cephalon's Compliance Department, Relator was shut out of meetings he had previously attended on a regular basis.

424. Second, he was passed over for a promotion within the Company, even though he was eminently qualified for the new position and the person who was ultimately hired for the job was significantly less qualified than Relator.

425. As a result of Cephalon's efforts to minimize his role and foreclose any opportunity of advancing his career within the Company, Relator was effectively forced to resign his position.

426. Further, as a direct and proximate result of this unlawful retaliation, Relator suffered economic damages, emotional pain and mental anguish.

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

427. Relator incorporates herein by reference the preceding paragraphs of the Corrected Second Amended Complaint as though fully set forth herein.

428. 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).

429. As a result of Defendants' actions as set forth above in this Corrected Second Amended 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)(1)(B))[2]

430. Relator incorporates herein by reference the preceding paragraphs of the Corrected Second Amended Complaint as though fully set forth herein.

431. 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).

432. 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

[1] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(1).
[2] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(2).

statements, paid and may still be paying or reimbursing for Treanda® and Fentora® prescribed to patients enrolled in Government Programs.

433. As a result of Defendants' actions as set forth above in this Corrected Second Amended 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)(1)(C))[3]

434. Relator incorporates herein by reference the preceding paragraphs of the Corrected Second Amended Complaint as though fully set forth herein.

435. 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.

436. 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 False Claims Act, 31 U.S.C. § 3729(a)(1)(G))[4]

437. Relator incorporates herein by reference the preceding paragraphs of the Corrected Second Amended Complaint as though fully set forth herein.

438. As detailed above, Defendants knowingly made, used, and/or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided

[3] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(3).
[4] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(7).

or decreased an obligation to pay or transmit money or property to the Government pursuant to 31 U.S.C. § 3729(a)(1)(G).

439. 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 V
(Violation of False Claims Act, 31 U.S.C. § 3730(h))

440. Relator incorporates herein by reference the preceding paragraphs of the Corrected Second Amended Complaint as though fully set forth herein.

441. During the course of his employment, Relator was discriminated against in the terms and conditions of his employment by Cephalon, all in retaliation for lawful acts taken by Relator to report violations of the False Claims Act and in retaliation for other lawful acts taken by Relator in furtherance of an action under the False Claims Act.

442. Cephalon's retaliatory acts have proximately caused Relator to suffer and to continue to suffer substantial damage in an amount to be proven at trial.

COUNT VI
(Violation of California False Claims Act)

443. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

444. This is a civil action brought by Relator, on behalf of the State of California, against Defendants under the California False Claims Act, Cal. Gov't Code § 12652(c).

445. 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 for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

446. 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 material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

447. 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. Gov't Code § 12651(a)(7).

448. 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.

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

COUNT VII
(Violation of Colorado Medicaid False Claims Act)

450. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

451. This is a civil action brought by Relator, on behalf of the State of Colorado, against Defendants under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).

452. 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 Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

453. 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 material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

454. 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 its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

455. 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 state and state subdivision funded health insurance programs.

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

COUNT VIII

(Violation of Connecticut False Claims Act for Medical Assistance Programs)

457. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

458. This is a civil action brought by Relator, on behalf of the State of Connecticut, against Defendants under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301d.

459. 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 Connecticut, or its political subdivisions, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

460. 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 secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).

461. 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, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).

462. 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.

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

COUNT IX
(Violation of Delaware False Claims and Reporting Act)

464. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

465. This is a civil action brought by of Relator, on behalf of the State of Delaware, against Defendants under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1203(b).

466. 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 Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

467. 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 Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

468. 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 Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

469. The State of Delaware, 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 healthcare programs funded by the State of Delaware.

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

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

471. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

472. This is a civil action brought by Relator, on behalf of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code § 2-308.15(b).

473. 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, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(l).

474. 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 used, and may still be making, using, or causing to be made or used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

475. 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 District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).

476. The District of Columbia, 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 health insurance programs funded by the District.

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

COUNT XI
(Violation of Florida False Claims Act)

478. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

479. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendants under the Florida False Claims Act, Fla. Stat. § 68.083(2).

480. 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 Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

481. 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 its agencies, in violation of Fla. Stat. § 68.082(2)(b).

482. 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 its agencies, in violation of Fla. Stat. § 68.082(2)(g).

483. The State of Florida, or 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.

484. 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 XII
(Violation of Georgia False Medicaid Claims Act)

485. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

486. This is a civil action brought by Relator, on behalf of the State of Georgia, against Defendants pursuant to the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

487. 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 Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

488. 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 Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

489. 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 Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

490. 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.

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

COUNT XIII
(Violation of Hawaii False Claims Act)

492. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

493. This is a civil action brought by Relator, on behalf of the State of Hawaii, against Defendants under the Hawaii False Claim Act, Haw. Rev. Stat. § 661-25.

494. 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 Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

495. 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).

496. 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).

497. 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.

498. 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 XIV
(Violation of Illinois False Claims Act)

499. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

500. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/4(b).

501. 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 for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

502. 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 material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

503. 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 material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

504. The State of Illinois, or its political subdivisions, 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.

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

COUNT XV

(Violation of Indiana False Claims and Whistleblower Protection Act)

506. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

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

508. 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, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

509. 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 obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

510. 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, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

511. The State of Indiana, or its political subdivisions, 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.

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

COUNT XVI
(Violation of Iowa False Claims Act)

513. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

514. This is a civil action brought by Relator, on behalf of the State of Iowa, against Defendants under the Iowa False Claims Act, Iowa Code § 685.3(2)(a).

515. Defendants, in reckless disregard or deliberate ignorance for 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 for payment or approval, in violation of Iowa Code § 685.2(1)(a).

516. 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 material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

517. 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 me 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 Iowa, or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).

518. The State of Iowa, 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 for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

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

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

520. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

521. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs, against Defendants under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.

522. 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. Ann. § 46:438.3(A).

523. 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. Ann. § 46:438.3(B).

524. 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. Ann. § 46:438.3(D).

525. 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.

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

COUNT XVIII
(Violation of Maryland False Health Claims Act)

527. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

528. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendants under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.

529. 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 for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

530. 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 material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

531. 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 me 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 Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

532. The State of Maryland, 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 for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

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

COUNT XIX
(Violation of Massachusetts False Claims Act)

534. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

535. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).

536. 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 for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

537. 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. Gen. Laws ch. 12 § 5B(2).

538. 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 its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

539. 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.

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

COUNT XX
(Violation of Michigan Medicaid False Claims Act)

541. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

542. This is a civil action brought by Relator, on behalf of the State of Michigan, against Defendants under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.610a(1).

543. 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, false statements or false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

544. 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 false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

545. 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 were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).

546. 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 made, presented or caused to be made or presented, and may still be presenting or causing to be presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

547. 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.

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

COUNT XXI
(Violation of Minnesota False Claims Act)

549. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

550. This is a civil action brought by Relator, on behalf of the State of Minnesota, against Defendants under the Minnesota False Claims Act, Minn. Stat. § 15C.05(a).

551. 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 Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

552. 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 claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

553. 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 its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

554. 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 state and state subdivision funded health insurance programs.

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

COUNT XXII
(Violation of Montana False Claims Act)

556. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

557. This is a civil action brought by Relator, on behalf of the State of Montana against, Defendants under the Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).

558. 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 Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

559. 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 Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

560. 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 its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

561. 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.

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

COUNT XXIII
(Violation of Nevada False Claims Act)

563. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

564. This is a civil action brought by Relator, on behalf of the State of Nevada, against Defendants under the Nevada False Claims Act, Nev. Rev. Stat. § 357.080(1).

565. 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 claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

566. 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 false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

567. 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 its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

568. 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.

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

COUNT XXIV
(Violation of New Jersey False Claims Act)

570. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

571. This is a civil action brought by Relator, on behalf of the State of New Jersey, against Defendants pursuant to the New Jersey Fraud False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

572. 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, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

573. 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 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 New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

574. 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 Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

575. 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.

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

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

577. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

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

579. 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 New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

580. 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 false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

581. 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 its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

582. 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.

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

COUNT XXVI
(Violation of New York False Claims Act)

584. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

585. This is a civil action brought by Relator, on behalf of the State of New York, against Defendants under the New York False Claims Act, N.Y. State Fin. Law § 190(2).

586. 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 for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

587. 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 material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).

588. 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 material to an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

589. 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.

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

COUNT XXVII
(Violation of North Carolina False Claims Act)

591. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

592. 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. § 1-608(b).

593. 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 for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

594. 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 material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

595. 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 its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

596. 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.

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

COUNT XXVIII
(Violation of Oklahoma Medicaid False Claims Act)

598. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

599. This is a civil action brought by Relator, on behalf of the State of Oklahoma, against Defendants pursuant to the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).

600. 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 Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

601. 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, false records or

statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

602. 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 Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

603. 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.

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

COUNT XXIX
(Violation of Rhode Island False Claims Act)

605. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

606. This is a civil action brought by Relator, on behalf of the State of Rhode Island, against Defendants pursuant to the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).

607. 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 Rhode Island or a member of Rhode Island's National Guard,

false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

608. 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, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

609. 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 Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

610. 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.

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

COUNT XXX
(Violation of Tennessee Medicaid False Claims Act)

612. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

613. This is a civil action brought by Relator, on behalf of the State of Tennessee, against Defendants under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b).

614. 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, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program,, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

615. 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 or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

616. 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 or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

617. The State of Tennessee, 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 the Medicaid program.

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

COUNT XXXI
(Violation of Texas Medicaid Fraud Prevention Act)

619. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

620. This is a civil action brought by Relator, on behalf of the State of Texas against, Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).

621. 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, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

622. 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, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

623. 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, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, false statements or misrepresentations 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 Ann. § 36.002(4)(B).

624. 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, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

625. The State of Texas, or it 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.

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

COUNT XXXII
(Violation of Virginia Fraud Against Taxpayers Act)

627. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

628. 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(A).

629. 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 of Virginia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

630. 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 of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

631. 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 Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

632. The Commonwealth of Virginia, 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.

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

COUNT XXXIII
(Violation of Washington Medicaid False Claims Act)

634. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

635. This is a civil action brought by Relator, on behalf of the State of Washington, against Defendants under the Washington Medicaid False Claims Act, S. 5978, 2nd Cong. § 205.

636. 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 for payment of approval, in violation of S. 5978, 2nd Cong. § 202(1)(a).

637. 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 material to false or fraudulent claims, in violation of S. 5978, 2nd Cong. § 202(1)(b).

638. 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 Washington, or its political subdivisions, in violation of S. 5978, 2nd Cong. § 202(1)(g).

639. The State of Washington, 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.

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

COUNT XXXIV
(Violation of Wisconsin False Claims for Medical Assistance Law)

641. Relators incorporate herein by reference the preceding paragraphs of this Corrected Second Amended Complaint as though fully set forth herein.

642. This is a civil action brought by Relators, on behalf of the State of Wisconsin, against Defendants under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(5)(a).

643. 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 any officer, or employee, or agent of the State of Wisconsin, or its political subdivisions, false or fraudulent claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(a).

644. 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 approval or payment of false claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(b).

645. The State of Wisconsin, 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.

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

WHEREFORE, Relators prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting or causing to be submitted any more false claims, or further violating 31 U.S.C. § 3729 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Colo. Rev. Stat. § 25.5-4-304 *et seq.*; Conn. Gen. Stat. § 17b-301a *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Ga. Code Ann. § 49-4-168 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Ind. Code § 5-11-5.5 *et seq.*; Iowa Code § 685.1 *et seq.*; La. Rev. Stat. Ann. § 46:437.1 *et seq.*; Md. Code Ann., Health-Gen. § 2-601 *et seq.*; Mass. Gen. Laws ch. 12, § 5A *et seq.*; Mich. Comp. Laws § 400.601 *et seq.*; Minn. Stat. § 15C.01 *et seq.*; Mont. Code Ann. § 17-8-401 *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.J. Stat. Ann. § 2A:32C-1 *et seq.*; N.M. Stat. Ann. § 27-14-1 *et seq.*; N.Y. State Fin. Law § 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 Ann. § 36.001 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.*; S. 5978, 2nd Cong. § 201 *et seq.*; and Wis. Stat. § 20.931 *et seq.*

B. That judgment be entered in Relators' 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 ($5,000) or more than ten thousand dollars

($10,000) 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 Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), Cal. Gov't Code § 12652(g)(4), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. § 17b-301e(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, Iowa Code § 685.3(4)(a)(1), La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Va. Code Ann. § 8.01-216.7, S. 5978, 2nd Cong. § 207(1), and Wis. Stat. § 20.931(11), including reasonable attorneys' fees and litigation costs.

D. That judgment be entered in Relators' 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. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such 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 Relators' favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado 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;

F. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), 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. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate 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 Relators' favor and against Defendants in the amount of the damages sustained by 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 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 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 Relators' favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 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 § 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 Relators' 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. § 68.082(2), 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 false claim as provided by Fla. Stat. Ann. § 68.082(2), 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 Relators' 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. § 49-4-168.1(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 false claim as provided by Ga. Code Ann. § 49-4-168.1(a), 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 Relators' 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 Relators' 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. § 175/3(a)(1)(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 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such 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 Relators' favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) as provided by Ind. Code § 5-11-5.5-2(b), to the extent such 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 Relators' favor and against Defendants in the amount of damages sustained by the State of Iowa, multiplied as provided for in Iowa Code § 685.2(1), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), as provided by Iowa Code § 685.2(1), to the extent such multiplied penalties shall fairly compensate the State of Iowa 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;

O. That judgment be entered in Relators' 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. Ann. § 46:438.6(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. Ann. § 46:438.6(B)(1), 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. Ann. § 46:438.6(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. Ann. § 46:438.6(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;

P. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Maryland 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 Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such penalties fairly compensate the State of Maryland 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 Relators' favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than five thousand dollars ($5,000) dollars and not more than ten thousand dollars ($10,000), plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch 12. § 5B, to the extent such 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;

R. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and

Relators, as provided by §§ 400.610a(9) and 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;

S. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relators, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota 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;

T. That judgment be entered in Relators' 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, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), 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 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;

U. That judgment be entered in Relators' 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. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act, pursuant to Nev. Rev. Stat. § 357.040(1), 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;

V. That judgment be entered in Relators' 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. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*) for each false or fraudulent claim, 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;

W. That judgment be entered in Relators' 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 full discovery;

X. That judgment be entered in Relators' 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. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 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. State Fin. Law § 189(1), 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;

Y. That judgment be entered in Relators' 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. § 1-607, 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;

Z. That judgment be entered in Relators' 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, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Okla. Stat. tit. 63, § 5053.1(B), 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;

AA. That judgment be entered in Relators' 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 § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by R.I. Gen. Laws § 9-1,1-3(a), 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;

BB. That judgment be entered in Relators' 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 twenty-five thousand dollars ($25,000) 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;

CC. That judgment be entered in Relators' 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 Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 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 Ann. § 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 Ann. §§ 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;

DD. That judgment be entered in Relators' 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 five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) 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;

EE. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Washington or its political subdivisions multiplied as provided for in S. 5978, 62nd Cong. § 202(1), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) per claim as

provided by S. 5978, 62nd Cong. § 202(1), to the extent such penalties shall fairly compensate the State of Washington 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;

FF. That judgment be entered in Relators' favor and against Defendants 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 Defendants, together with penalties for specific claims to be identified at trial after full discovery;

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

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

II. That Relators 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: July 12, 2013

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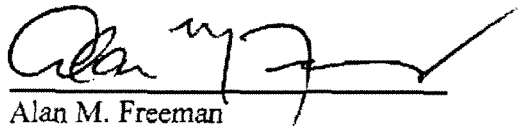
CERTIFICATE OF SERVICE

I hereby certify that on or before July 15, 2013, I caused a true and correct copy of Plaintiff's Corrected Second Amended Complaint to be served on each of the parties listed below via certified, first-class mail, postage prepaid.



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