THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* BRUCE BOISE, KEITH DUFOUR and ANDREW AUGUSTINE, and on behalf of the STATES of CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, the Commonwealth of MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW JERSEY, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, the Commonwealth of VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, *Plaintiffs*, v. CEPHALON, INC., a Wholly-Owned, Indirect Subsidiary of TEVA PHARMACEUTICAL INDUSTRIES LTD., and JOHN DOES # 1-100, FICTITIOUS NAMES, *Defendants*.	Hon. Thomas N. O'Neill, Jr. Civil Action No. 08-287

SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

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 Bruce Boise, Keith Dufour and Andrew Augustine ("Relators"), by and through their 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 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 Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.* (2006); 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 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 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); 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-conspirator 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 for off-label, non-medically accepted uses that are ineligible for reimbursement by Government Programs.

3. Specifically, Cephalon illegally promoted (i) Provigil, which is approved to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder; (ii) Nuvigil, a successor drug to Provigil, for which Cephalon obtained FDA approval in June 2007 to treat only the same conditions for which Provigil was approved; and (iii) Fentora, a successor drug to Actiq, for which Cephalon obtained FDA approval in 2006 to market for treatment of breakthrough cancer pain ("BTCP") in adult patients who are already receiving and who are tolerant of opioid therapy for their persistent cancer pain.

4. Cephalon's conduct has been an outgrowth and continuation of similar misconduct that Relator Boise has previously alleged in a related action before this Court (settled

with the United States in September of 2008) that Cephalon engaged in with respect to Provigil, Gabitril and Actiq. Allegations in this Second Amended Complaint regarding sales conduct relating to those three drugs during the period of covered conduct encompassed by that settlement are repeated here solely for the purpose of providing background information that helps put Cephalon's more recent behavior as to Fentora and Nuvigil, and—post December 31, 2006—Provigil, into context, and that helps explain why Cephalon's improper marketing behavior with respect to the drugs sued upon in this action has had an immediate and wide-ranging impact.

5. Provigil (modafinil) is a vigilance promoting drug (or eugeroic) that is approved by the United States' Food and Drug Administration ("FDA") to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, shift work sleep disorder and obstructive sleep apnea. Following December 31, 2006, as alleged herein, Cephalon aggressively promoted Provigil off-label and conspired to hide its fraudulent scheme during a period of government scrutiny by having its co-promoter and co-conspirator, Takeda Pharmaceuticals North America, Inc. ("Takeda") engage in similar conduct.

6. Nuvigil (armodafinil), a once-daily successor drug to Provigil (which is taken twice daily), obtained FDA approval in June 2007 to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder. Cephalon, however, did not launch the product in the marketplace until June 2009. Since Nuvigil was first launched, as alleged herein, Cephalon has aggressively promoted Nuvigil for off-label use in much the same manner that it had marketed Provigil.

7. After it gained FDA approval for limited indications in June of 2006, Fentora (fentanyl buccal tablet) was added to the mix of drugs Cephalon promoted off-label. Cephalon

continued the successful, albeit unlawful, scheme it had developed for sale of Actiq by not only selling to the same doctors who had prescribed Actiq off-label, but aggressively marketing to pain doctors and other doctors regardless of whether they treated *any* cancer patients.

8. Cephalon's off-label promotion of Provigil, Nuvigil and Fentora is particularly egregious, given that in September 2008 it pled guilty to having engaged in systematic misbranding of Gabitril, Provigil and Actiq stemming from its off-label promotion.

9. 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 continue promoting Provigil off-label up to and including the time the company ceased marketing the drug and then convert those prescribers to write off-label prescriptions for Nuvigil, which Cephalon launched in June 2009. Similarly, Cephalon's scheme was to convert physicians who prescribed Actiq for off-label uses to prescribe Fentora for those same off-label uses.

10. 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 United States Office of the Inspector General for the Department of Health and Human Services ("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.

11. Not only did Cephalon know that its misleading, off-label promotion would cause physicians to write prescriptions for Provigil, Nuvigil and Fentora that 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 these drugs by Government Programs have been substantial. Cephalon has profited handsomely, and the fraudulent scheme is ongoing.

12. Finally, and in derogation of the patient privacy protections under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Cephalon has bribed health care professionals to submit, and its own sales representatives have filled out and submitted, fraudulent prior authorization requests in order to evade Government Programs' formulary restrictions and obtain payment for its drugs.

13. Cephalon's illegal conduct, including kickbacks to health care professionals, falsification of prior authorization requests, and misleading and off-label promotion, 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.

14. Cephalon's conduct had a material effect on the Governments' decision to pay for Cephalon's drug products. Had the Federal Government and *Qui Tam* States known that Cephalon had induced the prescribing of its drugs through widespread kickbacks and/or off-label promotions, that Cephalon had knowingly caused the submission of material false certifications of compliance, or that Cephalon represented or caused providers to misrepresent the medical necessity of prescriptions for its products by falsifying prior authorization requests, the Federal Government and *Qui Tam* States would not have made such reimbursements.

15. As alleged in this Second Amended Complaint, Cephalon has been engaged in a multi-faceted, nationwide, unlawful marketing scheme, involving its sales and marketing employees across the United States, including in each of the *Qui Tam* States.

II. JURISDICTION AND VENUE

16. 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.

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

18. 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.

19. The causes of action alleged herein are timely brought because, among other things, (a) the conduct has occurred within the last six years and/or within six years of the filing of the original complaint in this action; and/or (b) the efforts by Defendants to conceal from the United States its wrongdoing in connection with the allegations made herein justify tolling; and/or (c) any statutes of limitations have been tolled by operation of the Wartime Suspension of Limitations Act, 18 U.S.C. §3287.

III. PARTIES

A. Plaintiff/Relator Bruce Boise

20. Plaintiff/Relator Bruce Boise is a resident of Key West, Florida. From 1996 to June 2003 Mr. Boise was employed in Ohio by Cephalon in sales representative and sales manager positions. Concerned about Cephalon's misconduct as alleged herein, Boise voluntarily met with FDA officials in January 2003, and has cooperated thereafter with their efforts to investigate his allegations. He was terminated by the company in 2003 because of his refusal to incorporate improper off-label marketing strategies into his sales approach and for sharing information regarding Cephalon's misconduct with the FDA.

21. Relator Boise is an original source of the allegations in this 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 action in accordance with 31 U.S.C. § 3730(b)(2). Relator Boise has direct and independent knowledge of the allegations and transactions herein.

B. Plaintiff/Relator Keith Dufour

22. Plaintiff/Relator Keith Dufour is a resident of Louisiana. Relator Dufour was employed by Cephalon as a Central Nervous System ("CNS") specialist from July 1999 through February 2011. Among his responsibilities while employed by Cephalon, Relator Dufour sold, among other products, Provigil and Nuvigil. Relator Dufour also participated in the launch of Provigil. He was twice awarded Cephalon's prestigious Presidents Club Award, which is presented to sales representatives who rank highest in the nation for total sales. Relator Dufour also served as an area trainer for Cephalon from 2008 through 2009.

23. Relator Dufour is an original source of the allegations in this 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 action in accordance with 31 U.S.C. § 3730(b)(2). Also prior to filing this action, Relator Dufour brought the wrongdoing described herein to the attention of Cephalon. Relator Dufour has direct and independent knowledge of the allegations and transactions herein.

C. Plaintiff/Relator Andrew Augustine

24. Plaintiff/Relator Andrew Augustine is a resident of Ohio. Relator Augustine was employed by Cephalon as a sales representative from April 2003 through August 2010. Among his responsibilities while employed by Cephalon, Relator Augustine sold, among other products, Provigil and Nuvigil. Relator Augustine also participated in the launch of Nuvigil. He twice received the Representative of the Year honors for the Ohio West territory in 2006 and 2007. Relator Augustine was also an area trainer for Cephalon from 2008 through 2010 and served on Cephalon's Marketing Advisory Panel for Provigil in 2006 and for Nuvigil in 2008.

25. Relator Augustine is an original source of the allegations in this 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 Second Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2). Relator Augustine has direct and independent knowledge of the allegations and transactions herein.

D. Defendant Cephalon, Inc.

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

owned, direct subsidiary of Cupric Holding Co., Inc. Cupric Holding Co., Inc. is a wholly owned, direct subsidiary of Teva Pharmaceutical Industries Ltd., which acquired Cephalon in late 2011.

27. Teva Pharmaceutical Industries Ltd. is a global pharmaceutical company organized under the laws of Israel. Teva is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

28. 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 Provigil, Nuvigil and Fentora, throughout the United States.

29. Cephalon has a history of illegal off-label promotion and causing the submission of false claims to Government 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. As part of that settlement, Cephalon entered into a five-year Corporate Integrity Agreement ("CIA") with the United States Office of the Inspector General for the Department of Health and Human Services ("OIG"), which 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.

30. At the time of the settlement and criminal plea, Valli Baldassano, Cephalon's chief compliance officer, stated that the "[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.

31. Notwithstanding its having entered into the CIA, as alleged herein, Cephalon has promoted Provigil, Nuvigil 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

32. 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.

33. 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).

34. 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).

35. 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.

36. 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).

37. 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).

38. 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).

39. 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.

40. 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.

41. 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.

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

43. 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.

44. 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.

45. 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."

46. "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.

47. 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 speaker programs, and drug-company sponsored clinical trials.

48. 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).

49. 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).

50. 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.

51. 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

52. 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

53. 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.

54. 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).

55. 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.

56. During the time period relevant to this Second Amended Complaint, Cephalon caused the submission of claims for off-label uses of Provigil, Nuvigil, 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 Use of Provigil Was Ineligible for Medicaid Reimbursement

57. From the launch of Provigil until at least February 21, 2014, none of the statutorily named Compendia supported the use of Provigil for any uses beyond its limited FDA-approved indications.

58. Accordingly, from the approval of Provigil until at least February 21, 2014, any off-label use of Provigil was therefore not a medically accepted indication under the Medicaid program, and Provigil was therefore ineligible for reimbursement for such uses. Any claims submitted to Medicaid for payment of Provigil used to treat any off-label conditions were therefore false as a matter of law.

3. Off-Label Use of Nuvigil Was Ineligible for Medicaid Reimbursement

59. From the launch of Nuvigil until at least February 21, 2014, none of the statutorily named Compendia supported the use of Nuvigil for any uses beyond its limited FDA-approved indications.

60. Accordingly, from the approval of Nuvigil until at least February 21, 2014, any off-label use of Nuvigil was therefore not a medically accepted indication under the Medicaid program, and Nuvigil was therefore ineligible for reimbursement for such uses. Any claims submitted to Medicaid for payment of Nuvigil used to treat any off-label conditions were therefore false as a matter of law.

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

61. From the approval of Fentora until at least February 21, 2014, 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).

62. Accordingly, from the approval of Fentora until at least February 21, 2014, the use of Fentora to treat breakthrough pain 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

63. 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.

64. Pharmacy-dispensed outpatient drugs such as Provigil, Nuvigil, and 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.

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

2. Off-Label Use of Provigil Was Ineligible for Medicare Reimbursement

66. From the approval of Provigil until at least February 21, 2014, none of the statutorily named Compendia supported the use of Provigil for any uses beyond its limited FDA-approved indications. From the approval of Provigil until at least February 21, 2014, any off-label use of Provigil was not a medically accepted indication under the Medicare program, and Provigil was therefore ineligible for reimbursement for such uses. Any claims submitted to Medicare for payment of Provigil used to treat any off-label conditions were therefore false as a matter of law.

3. Off-Label Use of Nuvigil Was Ineligible for Medicare Reimbursement

67. From the approval of Nuvigil until at least February 21, 2014, none of the statutorily named Compendia supported the use of Nuvigil for any uses beyond its limited FDA-approved indications. From the approval of Nuvigil until at least February 21, 2014, any off-label use of Nuvigil was not a medically accepted indication under the Medicare program, and Nuvigil was therefore ineligible for reimbursement for such uses. Any claims submitted to Medicare for payment of Nuvigil used to treat any off-label conditions were therefore false as a matter of law.

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

68. From the approval of Fentora until at least February 21, 2014, 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).

69. From the approval of Fentora until at least February 21, 2014, the use of Fentora to treat breakthrough and other types of pain in non-cancer patients was 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

70. 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:

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

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

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

74. 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).

75. During the time period relevant to this Second Amended Complaint, claims submitted to the preceding Government Programs for the any off-label use of Provigil, Nuvigil and Fentora were ineligible for reimbursement and therefore false as a matter of law.

VI. POST-SETTLEMENT: BUSINESS AS USUAL AS CEPHALON CONTINUES ITS FRAUDULENT MARKETING PRACTICES UNABATED

A. "Business As Usual"

76. In the months leading up to the signing of the Settlement Agreement with the United States and the States in September 2008, the highest levels of Cephalon's senior management struggled internally with how to manage the company's sales and marketing practices moving forward given that the company's business model was entirely reliant on unlawful conduct. At the time, Cephalon was facing substantial civil and criminal fines totaling some $425 million. Its promotional activities were also going to be subjected to Government oversight as a result of the Corporate Integrity Agreement ("CIA"), which was a requirement of the settlement.

77. The debate centered on two separate courses of action the company could take. On the one hand, there was a contingent—comprised of CEO Frank Baldino and Executive Vice President for Worldwide Operations, Bob Roche—who insisted that the company had done

nothing illegal in the first place and thus had been unfairly targeted. The proposed strategy from this group was simply to continue Cephalon's aggressive off-label marketing, while being mindful of not leaving a paper trail. The other contingent offered an alternate course that adhered to the FDA's rules and proposed instituting strategies that would focus the promotional activities on on-label uses only. Unsurprisingly, those who advocated fundamental change were silenced or chastised, and the "business as usual" strategy prevailed.

78. For Provigil, the company was fully aware that the vast majority of prescriptions written for the drug were off-label. In fact, internal audits revealed that at least 70% of Provigil's sales were for unapproved uses. But rather than remove physicians who did not treat on-label conditions—namely psychiatrists and neurologists—Cephalon doubled down on its previous strategies and sought to increase its market share by continuing to promote to these physicians (and, in the period it was being investigated and up until a few weeks before the settlement with the Government was consummated, by putting certain of its off-label scheme under the aegis of a co-promotion agreement with Takeda).

79. With regard to Nuvigil, the company put in place a plan to convert the vast off-label market it enjoyed with Provigil into Nuvigil sales. And although Cephalon briefly removed psychiatrists from its Nuvigil call lists and created a "do not call/do not promote" database, this fix was only temporary, as sales representatives were trained on how to detail these physicians in order to retain and even grow these off-label customers.

80. For Fentora, Cephalon was well aware that oncologists were the only health care professionals who prescribed Fentora for its on-label indication, and that health care professionals outside oncology prescribed Fentora almost exclusively for off-label uses. In fact, in mid-2007 the United States presented concrete evidence to the company, in the form of

recorded sales calls, demonstrating that sales representatives had been aggressively promoting the drug to pain specialists to treat off-label pain conditions well beyond the limited approval for BTCP in opioid tolerant patients. And while sales representatives were told at a national sales meeting in 2007 that this type of promotion would no longer be tolerated, the company shortly thereafter reversed course and, based on a directive from CEO Baldino, Cephalon's sales and marketing team instructed the sales force to continue marketing Fentora in the same manner, targeting the same pain doctors just as the company had before the settlement – physicians the company knew did not write the drug on label.

81. As a direct result of Cephalon's deliberate decision to continue its illegal marketing practices, the company violated the terms of the Corporate Integrity Agreement and caused Government Programs to continue to reimburse for the off-label uses of these drugs.

B. Cephalon Concealed Its Continued Off-Label Promotional Activities

82. Even prior to the announcement of the settlement agreement, Cephalon had begun to take steps to conceal its off-label promotion by removing discussion of off-label uses from training materials, visual sales aids, field coaching reports, and promotional speaker slide decks. Further, during national and regional sales meetings, Cephalon limited training to Provigil, Nuvigil and Fentora's on-label indications, and the company even purported to instruct sales representatives to exclude off-label discussion from their promotional details to physicians.

83. These changes purported to bring Cephalon's promotion of Provigil, Nuvigil and Fentora in line with Cephalon's official compliance policies, which declared a commitment to limiting promotion of all of Cephalon's drugs to approved uses and reflect Cephalon's knowledge of its legal obligation to do so.

84. However, while the messages espoused in official promotional literature purported to reorient the company solely toward promotion of on-label uses, Cephalon never directed sales representatives to stop using the old, off-label promotional messages. On the contrary, during role play exercises at district sales meetings, sales representatives continued unabated to rehearse before their managers the same, illegal off-label promotional messages that Provigil, Nuvigil and Fentora were safe and effective for off-label uses.

85. As Cephalon conveyed the company's situation to its sales representatives, restrictions on off-label promotion imposed by the FDA took an unreasonably cautious view of the evidence necessary to establish the safety and efficacy of a drug for a given use, and it was only as the result of this unreasonably strict regulatory regime that Cephalon was not allowed to promote Provigil, Nuvigil and Fentora for the off-label uses that it sought to promote.

86. By promoting Provigil, Nuvigil and Fentora for off-label use, Cephalon told its sales representatives, they were ensuring that patients benefited from uses of Provigil, Nuvigil and Fentora that had been shown to be safe and effective, but had not yet received the imprimatur of the FDA. As a result, sales representatives believed that Cephalon's evasion of the FDA's prohibition on off-label promotion was justified. Sales representatives were, in many respects, as deceived by Cephalon's off-label promotional claims as were physicians, unaware that the off-label uses for which they promoted Provigil, Nuvigil and Fentora were neither supported by substantial clinical evidence nor medically accepted, and unaware that the promotional claims they made were blatantly misleading.

87. When Cephalon did provide sales representatives with information regarding off-label use of Provigil, Nuvigil and Fentora, it marked that information as "for educational purposes only" and "not to be shared" with physicians, purportedly to instruct sales

representatives not to use the information to promote Provigil, Nuvigil and Fentora to physicians as effective for the off-label use discussed therein. Verbally, however, Cephalon's district managers explicitly contradicted these directions and instructed sales representatives to use the information to promote Provigil, Nuvigil and Fentora for off-label use.

88. Cephalon's continued off-label promotion of Provigil, Nuvigil and Fentora was not limited to Relators' districts. Rather, based on their experience as sales representatives in two different districts, and based on conversations in the course of their job duties with sales representatives from across the country, it is clear that Cephalon's continued off-label promotion of Provigil, Nuvigil and Fentora, and its attempted concealment thereof, was a nationwide scheme.

VII. PROVIGIL AND NUVIGIL: CEPHALON'S FRAUDULENT MARKETING CAUSED THE SUBMISSION OF FALSE CLAIMS FOR OFF-LABEL USES

89. To promote Provigil off-label and gain market share prior to the approaching expiration of its market exclusivity in March 2012, Cephalon leveraged an array of off-label promotional methods, including sales representative details and speaker programs, to drive sales. Because Provigil was scheduled to go off patent and was subject to patent challenges by generic manufacturers that ran the risk of further expediting loss of Cephalon's patent protection, Cephalon engaged in a marketing strategy to convert Provigil prescribers the company gained through its prior off-label marketing efforts into prescribers of Nuvigil. In this manner, Cephalon attempted to limit financial losses once generic competition to Provigil entered the market.

90. As to both Provigil and later Nuvigil, Cephalon's off-label promotion was not only illegal, but substantially false and misleading. Cephalon presented the various off-label uses as demonstrating clinical benefits to patients both in terms of efficacy and safety without

disclosing the significant flaws in clinical studies the company trained its sales force to promote, and altogether concealing the existence of clinical studies that showed the drug was not efficacious and/or safe for such off-label uses.

91. As a result of Cephalon's sales representatives' off-label promotion of Provigil and Nuvigil, physicians prescribed these drugs for various off-label uses and submitted false claims to Government Programs for reimbursement.

A. Background Regarding Provigil (modafinil)

92. Modafinil, marketed as Provigil, is comprised of a series of benzhydryl sulfinyl compounds, including adrafinil, which was first offered as an experimental treatment for narcolepsy in France in 1986. Provigil is currently classified as a Schedule IV controlled substance under United States federal law.

93. In 1998, Provigil was originally approved as a wakefulness-promoting agent in adults with excessive daytime sleepiness ("EDS") associated with narcolepsy. In 2003, the drug was approved for EDS associated with obstructive sleep apnea ("OSA") and shift work sleep disorder ("SWSD"). To date, these are the only the only FDA-approved uses for Provigil. Despite these limitations, Cephalon employed a series of promotional schemes to market Provigil for numerous off-label uses, including for treatment of attention deficit hyperactivity disorder in children; for treatment of fatigue associated with multiple sclerosis, Parkinson's disease, unipolar depression, bipolar depression, and schizophrenia; for treatment of other symptoms of schizophrenia; for cognitive enhancement in Parkinson's disease patients; and for treatment of jet lag.

B. Background Regarding Nuvigil (armodafinil)

94. Armodafinil, marketed by Cephalon as Nuvigil, is the R-enantiomer of modafinil, which is a mixture of the R- and S-enantiomers. Enantiomers are molecules that are mirror images of each other but are not superimposable, analogous to left and right hands. Nuvigil is currently classified as a Schedule IV controlled substance under United States law.

95. Nuvigil, a once-daily successor drug to Provigil (which is taken twice daily), was approved by the FDA in June 2007 to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder. Cephalon, however, did not launch the product in the market until June of 2009—mere months after the company halted its promotion of Provigil. Because Nuvigil is not a precise chemical or delivery-form equivalent of Provigil, it has its own new patent protection which protects the product's exclusivity until 2023. Consequently, Nuvigil does not face immediate competition from generic equivalents and can be sold at the higher prices assigned to branded drugs.

96. Since the time Nuvigil was first launched in 2009, Cephalon has aggressively promoted Nuvigil for off-label uses in much the same manner that it had marketed Provigil.

C. Cephalon's Senior Management Directed and Controlled Sales Representatives' Off-Label Marketing of Provigil and Nuvigil

97. At all times material hereto, the doctors to whom Cephalon promoted Provigil and Nuvigil reasonably believed that the knowledge that informed their clinical decisions and standards of care was derived from the scientific evidence published in medical journals, presented in review articles, and endorsed by thought leaders and trusted organizations at speaker programs. Cephalon engaged in a carefully orchestrated and comprehensive program to exploit physicians' trust in this process of knowledge creation and dissemination. Rather than being the

product of unbiased scientific inquiry, the scientific evidence supporting off-label use of Provigil and Nuvigil derived from Cephalon's carefully designed and orchestrated campaign, in which pre-determined, readily marketable key messages formed the basis for the scientific evidence, and not the other way around.

98. Even following the company's settlement with the United States, Cephalon's sales representatives were to (and did) provide healthcare professionals nationwide with messaging to influence the off-label prescribing of the Provigil and Nuvigil. This off-label messaging was provided to healthcare professionals at one-on-one details, in-services, speaker programs and round tables.

99. The specific intent of Cephalon's promotion was to influence physicians to write more prescriptions for Provigil and Nuvigil, including for numerous off-label uses.

100. Cephalon trained its Provigil and Nuvigil sales force to leverage off-label clinical information concerning uses (including off-label uses) when planning each sales call. Sales representatives were to pinpoint the study's key findings (including off-label findings), which were then turned into key selling messages. The training for, and pre-call planning of, the fraudulent scheme was both elaborate and deliberate. This planning gave sales representatives enough time to determine on which points to focus, as well as to prepare for any possible physician objections to the message. Sales representatives were to demonstrate to physicians that representatives constituted a knowledgeable resource, were familiar with the study concepts, and could speak the physician's language to answer any questions that arose regarding the study. They were specifically trained to manipulate the message by softening the language around unfavorable points and focusing instead on the strengths in order to make their message more compelling.

101. At the conclusion of each sales call, Cephalon's sales representatives were to close the sale by asking for the physician's agreement to prescribe Provigil and Nuvigil off-label.

102. The Provigil and Nuvigil sales representatives regularly role-played sales details in front of sales management at district and national meetings, at which they honed their off-label message. Managers evaluated sales representatives on their ability to utilize their training in the field. In addition, district managers regularly conducted "ride-alongs" with each of their respective sales representatives, in order to ensure that representatives were promoting the off-label message, as well as to "coach" them on how to improve that message. As such, the off-label promotion was not only the product of deliberate planning by Cephalon, it was directly supervised and encouraged.

D. Cephalon Targets Physicians Who Do Not Treat On-Label Uses of Provigil and Nuvigil

103. To encourage off-label marketing by its sales force, Cephalon de-emphasized sales calls to sleep specialists likely to prescribe Provigil and Nuvigil to treat patients with on-label indications and instead directed its sales representatives to concentrate their promotional efforts on health care professionals who were treating patients likely to suffer the kinds of disorders for which off-label prescriptions could be solicited. Such targeting was aimed at, for example, promotion to psychiatrists and other physicians who prescribed substantial amounts of anti-depressant drugs, to develop off-label sales of Provigil for fatigue associated with depression, bipolar depression, opiate and cocaine dependence, Parkinson's disease, schizophrenia, and other forms of disease-related fatigue, as well as a multitude of other off-label indications.

104. Cephalon's strategy of targeting physicians who treat off-label conditions was reinforced by the company at its highest levels. At the 2008 Cephalon National Sales Meeting,

Lynne Brooks, Cephalon's Vice President of Marketing, reiterated to the entire CNS sales force the mantra that "sleepiness is sleepiness," which Cephalon had long used to justify its off-label promotion of Provigil for excessive sleepiness associated with conditions outside Provigil's approved indications. Brooks intended and the CNS sales force understood her espousal of the "sleepiness is sleepiness" motto as an instruction to the sales force to continue promoting Provigil for treatment of excessive sleepiness and fatigue, regardless of their association with Provigil's on-label indications.

105. The "sleepiness is sleepiness" message is precisely the same marketing campaign that the FDA had warned Cephalon to discontinue. In February 2007, only two months after the close of the conduct covered by the Settlement Agreement, the FDA sent Cephalon a warning letter informing the company that a promotional piece that it distributed was false or misleading because it stated or suggested that Provigil is safe and effective for use in the treatment of various disorders associated with sleepiness generally, when in fact Provigil is only approved to treat a very small subset of patients with excessive sleepiness. The FDA directed Cephalon to cease immediately the dissemination of promotional materials for Provigil such as the material described in the FDA's letter. This same "sleepiness" message was specifically cited in the United States' Criminal Information against Cephalon. *See* Criminal Information at 7, *United States v. Cephalon, Inc.*, No. 8-cv-598 (E.D. Pa. Sept. 29, 2008).

106. Cephalon targeted physicians based not on how many prescriptions were written to treat on-label conditions, but in relation to the number of prescriptions written for certain classes of drugs, including serotonin-specific reuptake inhibitors ("SSRIs"), serotonin–norepinephrine reuptake inhibitors ("SNRIs") and stimulants, that treated only off-label conditions like depression, anxiety disorders, attention deficit hyperactivity disorder, chronic

neuropathic pain, and fibromyalgia. These Cephalon-generated call lists, which targeted off-label prescribers, existed before Cephalon entered into its CIA with the Government, and, importantly, remained unchanged thereafter.

107. Cephalon management ranked its Provigil, and later Nuvigil, targets on a scale of 1 to 10, with 10 representing physicians who were the highest potential writers. Within that range, the physicians were broken out into three bands: 1-3 (or "C"), 4-6 (or "B"), and 7-9 (or "A"). Cephalon computed each physician's decile ranking based on the number of prescriptions written for drugs classified as selective serotonin re-uptake inhibitors ("SSRIs") (a class of antidepressant drugs used to treat depression, anxiety disorders, and some personality disorders), serotonin–norepinephrine reuptake inhibitors ("SNRIs") (a class of antidepressant drugs used to treat major depression and other mood disorders) and stimulants (psychoactive drugs that induce temporary improvements in either mental or physical functions or both). The prescribing patterns for all physicians prescribing SSRIs, SNRIs and stimulants were closely monitored by Cephalon on a quarterly basis and the updated data was regularly provided to sales representatives as part of their call lists.

108. For a brief period, Cephalon appeared to have changed its practice of targeting physicians who primarily prescribed Provigil off-label. Ultimately, however, nothing had changed. Prior to the settlement, but after Cephalon was made aware that its promotional practices were under Government investigation, the company announced to its sales force that it would be removing all psychiatrists from the CNS sales representatives' call lists. This announcement, however, was made at approximately the same time that Cephalon entered into an agreement with Takeda to co-promote Provigil. Notably, all of the psychiatrists who were removed from Cephalon's call lists for Provigil were simply added to Takeda's call lists.

109. In effect, Cephalon's co-promotion agreement was thus an end-around the Government's ongoing investigation. By virtue of this agreement, Cephalon was able to keep Provigil in the offices of the company's highest writers—*i.e.*, psychiatrists prescribing off-label, until a time that Cephalon, unencumbered by an ongoing Government investigation, could resume illegal marketing practices on its own.

110. In fact, following the settlement with the United States and the termination of the co-promotion agreement with Takeda shortly thereafter, Cephalon's management retrenched its flagrant promotion to doctors it knew did not write Provigil. Specifically, Cephalon's Baldino and Roche (over the strong objection of other senior Cephalon management) directed the sales force to resume promoting the drug off-label to the same doctors to whom Cephalon had promoted it prior to the September 2008 guilty plea—*i.e.*, to primary care physicians, psychiatrists, and neurologists, rather than to sleep disorder specialists. Psychiatrists were restored as sales targets in 2009 in connection with Provigil and its successor Nuvigil, even though the company knew psychiatrists did not prescribe either drug for FDA-approved indications.

111. Even during the short period of time Cephalon temporarily removed all psychiatrists from call lists, internally, the company still calculated sales quotas and bonuses for its sales force based on these very same physicians. In fact, sales representatives received credit for prescriptions written by psychiatrists. Relator Augustine raised the issue with his district manager, Johnathan Cockrell, inquiring why it was possible to have one's sales performance affected by prescriptions Cephalon clearly knew were being written off label. The instruction from sales managers, including Cockrell, was to simply avoid leaving any paper trail, including the logging of any sales calls made on these physicians or providing them free samples.

Importantly, however, Cephalon left in place the financial incentives for the sales representative to seek prescriptions from the very same customers the company wanted the Government to believe they were intentionally avoiding. In doing so, Cephalon hoped to achieve the appearance of propriety, while, in reality, operating exactly the way it had before the settlement.

112. Cephalon's brief interlude of not calling on psychiatrists was officially put to rest in early 2009—as demonstrated in a PowerPoint presentation provided to sales representatives entitled "NUVIGIL CNS 90 Day Plan" for the second quarter of 2009, Cephalon announced that the company's "CNS team will *re-engage* with Psychiatrists on April 1st [2009]" (emphasis added).

113. Once Cephalon was back in the offices of psychiatrists, the company trained its sales representatives to differentiate between "fatigue" and "sleepiness" in their interactions with physicians. In training sessions, including workshops presented by Cephalon marketing representatives Dean Robinson and Brian Pimento, sales representatives were instructed to "speak the language" of their targets. For example, psychiatrists and neurologists do not typically use terms like "sleepiness" with their patients and therefore are unlikely to respond to such terms in their discussions with pharmaceutical sales representatives. Accordingly, Cephalon directed its sales force to "paint the picture" of *fatigue* when detailing Provigil, and later Nuvigil.

114. In order to "paint the picture" of fatigue, sales representatives like Relator Augustine were taught to point out to physicians that there is a difference between general fatigue, *i.e.*, climbing a flight of stairs and acute fatigue, *i.e.*, fatigue associated with multiple sclerosis or jet lag. Sales representatives were specifically trained to emphasize that Provigil's lack of withdrawal side effects made it an ideal choice for treatment of acute fatigue. Cephalon's

focus on having its sales force promote Provigil and Nuvigil using terminology used by these non-sleep physicians served the company well and helped increase the number of off-label prescriptions for fatigue-related uses.

115. For example, it was well known that Dr. Siraj Siddiqui, a physician in Mansfield, Ohio, prescribed Provigil, and later Nuvigil, for only off-label conditions, including fatigue. The fact that Dr. Siddiqui prescribed Provigil entirely off-label was known by Cephalon because the company purchased prescribing data that detailed the use for which it was prescribed. In fact, the data acquired by Cephalon also reveals the health plans of the patients treated by each physician, including whether patients were covered by Medicare or Medicaid. For example, 14% of Dr. Siddiqui's patients from Q4 2008 through Q1 2009 were Medicare Part D beneficiaries. And Cephalon made sure that its CNS sales force knew this information. The health plan data for each physician was made readily available on each sales representative's handheld device. Thus, Cephalon not only knew but intended that its promotion to physicians like Dr. Siddiqui would result in his prescribing its drugs off-label to Medicare and Medicaid beneficiaries.

116. Having the health plan information was particularly important because Cephalon also armed its sales force with managed care spreadsheets, distributed by the company's National Account Managers, which contained information about which plans covered which uses for Provigil and Nuvigil, including off-label uses. Cephalon intended that its sales representatives would know how to overcome physician objections to prescribing off-label by pointing out other ICD-9 codes that could be used to ensure coverage and overcome prior authorization requirements, including for Government Program beneficiaries.

117. Moreover, Cephalon refused to remove physicians from call lists, even after sales representatives made the company aware that the physicians like Dr. Siddiqui never prescribed Provigil or Nuvigil on-label. The only metric that mattered to Cephalon was whether the physician was prescribing the drugs. As long as the company could verify a physician prescribed Provigil or Nuvigil—irrespective of the condition treated—these physicians were maintained on the call lists (often over the sales representative's objection).

118. For example, Dr. Bharat C. Shah, a pain management physician in Lorain, Ohio, repeatedly confirmed that he did not treat patients who suffered from any of the conditions contained in Provigil's label. Even following Cephalon's civil settlement and criminal plea, this information was passed by Relator Augustine directly to Johnathan Cockrell, a Cephalon District Manager. But rather than having Dr. Shah removed from Augustine's call list, Cephalon insisted that Dr. Shah remain a targeted physician.

119. Further, Cephalon continued to take the prescribing data from these off-label physicians into account when the company created the sales representatives' call lists and established their sales quotas for Provigil and later Nuvigil. Accordingly, because the quotas were calculated based on all the physicians appearing on the call lists—including those who the company knew did not prescribe either drug on-label—sales representatives were required to promote to all, or nearly all, physicians on their call lists in order to meet or exceed their quotas even if doing so required them to promote the drugs off-label.

E. Cephalon Falsely and Misleadingly Promotes Provigil and Nuvigil for Off-Label Uses

120. Cephalon promoted Provigil and Nuvigil for numerous off-label uses that were not medically accepted and were therefore ineligible for reimbursement by Government Programs. By promoting Provigil and Nuvigil for these off-label uses, Cephalon caused

physicians to prescribe and pharmacies to submit to Government Programs claims for its drugs that were ineligible for reimbursement and were therefore false.

1. Cephalon Promotes Provigil and Nuvigil for the Off-Label Treatment of ADHD in Children and Adolescents

121. Neither Provigil nor Nuvigil has ever been approved for *any* pediatric use in any circumstance. Notwithstanding this prohibition, Cephalon promoted pediatric use of Provigil and later Nuvigil not only for the limited indications permitted only for adults (to the rather limited extent some older adolescent children have such conditions), but also for the exponentially larger—and entirely off-label—treatment of attention deficit hyperactivity disorder ("ADHD") in children of all ages. ADHD is a commonly-diagnosed psychiatric disorder in which there are significant problems of attention, hyperactivity, or acting impulsively that are not appropriate for a person's age. In effect, Cephalon's promotion to pediatric psychiatrists was an extension of its off-label promotional campaign to adult psychiatrists, and the uses for which Cephalon promoted Provigil and Nuvigil were therefore doubly off-label—lacking approval for both the conditions themselves as well as the pediatric patient population in which Cephalon promoted them.

122. Because neither Provigil nor Nuvigil has ever been approved for any pediatric use, any promotion of either drug for such use has been entirely off-label.

123. On March 23, 2006, the FDA Psychopharmacologic Drugs Advisory Committee convened to discuss safety and efficacy issues relating to Cephalon's new drug application that sought to expand Provigil's approved uses to include the treatment of attention deficit hyperactivity disorder ("ADHD") in children and adolescents.

124. 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.

125. Previously, in December 2004, Cephalon had submitted a supplemental NDA for "Sparlon," a renamed Provigil product, for the treatment of ADHD in children and adolescents. At the time, the PDAC raised concerns about three types of adverse events: (1) serious skin rashes; (2) psychiatric adverse events, and (3) three patients with transaminase elevations. The PDAC asked Cephalon to produce additional information pertinent to such events. On November 21, 2005, Cephalon subsequently provided responses to all of the FDA's requests.

126. The clinical reviewer for the original supplement concluded that, because of serious safety risks associated with use of Provigil, it should not be approved for ADHD. The Division of Psychiatry Products sought the advice of the Advisory Committee before reaching a final conclusion.

127. The Advisory Committee was asked to vote on whether Provigil had been shown to be acceptably safe in the treatment of ADHD in children and adolescents. The answer to this important question was a resounding "No." By a vote of 12 to 1, the Advisory Committee concluded that Provigil had not been demonstrated as safe for the treatment of ADHD in children and adolescents. Principal among the Advisory Committee's safety concerns was the possibility of developing the potentially fatal Stevens-Johnson syndrome. Dr. Glenn Mannheim, who conducted the FDA's clinical review of Provigil in ADHD reported:

> A recent CDC study estimated that 2.5 million children, ages 4-17, were on ADHD medication. Now, if we assume that only 10 percent of these children will try modafinil at some point, then we ask the next question, how many cases [of Stevens-Johnson syndrome] would result. We estimated that there would be a range between 500 and 3,000 cases which will occur based on the 0.2

> percent to the 1.3 percent incidence among the 10 percent who are switched to modafinil. Based on the known mortality associated with erythema multiforme, Stevens-Johnson, we would expect from 15 to over 400 deaths to occur. We conclude that even though a crude estimate can only be made at this time, a potential exists for a significant number of cases to occur post-approval since ADHD is so prevalent.

Transcript at 33, *Meeting: Psychopharmacologic Drugs Advisory Committee* (Mar. 23, 2006), *available at* http://www.fda.gov/ohrms/dockets/ac/cder08.html (last visited Feb. 24, 2014).

128. Further, the Advisory Committee identified a number of psychiatric adverse effects in young patients taking Provigil, including suicidal ideation, psychosis, and agitation. In addition, rates of insomnia (27%) and severe appetite loss (16%) were both cited as safety concerns. The Advisory Committee concluded that all of these safety issues were too serious to consider Provigil as a viable treatment option without further data. In fact, the FDA requested that Cephalon conduct an open-label study of at least 3,000 children in order to be certain of Provigil's safety.

129. Rather than agreeing to the safety trial, the company instead convened a team of dermatologic experts to review the records of one of the trial patients who was believed to have contracted Stevens-Johnson syndrome and submitted a packet of "new information" to assuage FDA concerns. However, the FDA subsequently rejected Cephalon's dermatologic evidence, and sent the company a second non-approvable letter. Cephalon ultimately elected not to pursue the ADHD indication and, on August 9, 2006, publicly announced its decision to completely drop development of Provigil for such use.

130. Despite the overwhelming rejection of Provigil's use in the treatment of ADHD based on the serious safety concerns cited by the FDA, and despite multiple warnings in Provigil's FDA-approved label that Provigil is not approved for treatment of pediatric patients

for any indication, Cephalon nevertheless encouraged its sales representatives to promote the drug for this rejected use. Specifically, beginning from at least 2007, sales representatives were compensated based on the number of Provigil prescriptions that were written in their territories by pediatricians and child psychiatrists to treat ADHD.

131. To promote Provigil for treatment of ADHD, sales representatives used a paper Cephalon had commissioned, entitled Biederman et al., *Modafinil improves symptoms of attention-deficit/hyperactivity disorder across subtypes in children and adolescents*, 152 J. Pediatrics 394 (2008).

132. The sales force was expected to, and did, use the Biederman study as part of Cephalon's promotion of Provigil (and later Nuvigil) for use in the treatment of ADHD. Those physicians included the following physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil:

(i) Dr. Rene Duffourc, Child Psychiatrist, Eureka Springs, Arkansas. Approximately 25% of Dr. Duffourc's patients are Medicare/Medicaid beneficiaries.

(ii) Dr. William F. Colomb, Child Psychiatrist, Mandeville, Louisiana. Approximately 20% of Dr. Colomb's patients are Medicare/Medicaid beneficiaries.

(iii) Dr. Tim Brown, Child Psychiatrist at the Center for ADHD, Inc., Lacomb, Louisiana. Approximately 30% of Dr. Brown's patients are Medicare/Medicaid beneficiaries.

(iv) Dr. Gordon Blundell, Child Psychiatrist, Madisonville, Louisiana. Approximately 20% of Dr. Blundell's patients are Medicare/Medicaid beneficiaries.

(v) Dr. Catharine Jackosky, Neuropsychiatrist, Lorain, Ohio. As of May 2010, 53.1% of Dr. Jackosky's patients were Medicaid recipients.

(vi) Dr. Cynthia Evans, Psychiatrist, Fremont, Ohio. As of May 2010, 7.3% of Dr. Evans' patients were Medicare Part D recipients and 6.6% were Medicaid patients.

(vii) Dr. Dorota S. Rytwinski, Psychiatrist, Fremont, Ohio. As of May 2010, 12.1% of Dr. Rytwinski's patients were Medicare Part D recipients and 10.4% were Medicaid patients.

(viii) Dr. Sanjay Parikh, Neurologist, Elyria, Ohio. As of May 2010, 16.6% of Dr. Parikh's patients were Medicaid recipients.

133. As the direct result of the company's promotion of Provigil and Nuvigil for ADHD, including data from the Biederman trial, each of these physicians began prescribing Provigil (and later Nuvigil) to treat their Medicare and Medicaid patients suffering from ADHD.

134. While sales representatives played an important role in Cephalon's off-label promotion of Provigil and Nuvigil for pediatric use, increased Government scrutiny in connection with Cephalon's negotiation and implementation of the Government's settlement agreement meant that paid speakers became an increasingly important off-label promotional tool, particularly with respect to use of Provigil and Nuvigil to treat ADHD. Although paid speakers were subject to the same legal requirements to limit their promotional presentations to on-label uses as Cephalon's sales representatives were, Cephalon apparently believed that speakers were,

as a practical matter, less likely to get caught, since attending physicians would be more likely to report an objectionable off-label message delivered by a sales representative than one delivered by a physician colleague.

135. Pediatric psychiatrists delivering Cephalon's paid promotional presentations officially adhered to the same on-label, adult slide deck as did other promotional speakers. In practice, however, they discussed, without exception, their own use of Provigil and Nuvigil in pediatric patients and recommended the drugs for off-label pediatric use. Moreover, the very reason that sales representative chose these pediatric psychiatrists to repeatedly return as speakers was that they would promote Provigil and Nuvigil for off-label pediatric use and thereby grow off-label prescribing.

2. Cephalon Promotes Provigil and Nuvigil for the Off-Label Treatment of Fatigue Associated with Multiple Sclerosis

136. Following December 31, 2006, Cephalon regularly promoted Provigil and later Nuvigil as effective for the off-label treatment of fatigue associated with multiple sclerosis ("MS").

137. To do so, Cephalon relied primarily on one small, uncontrolled clinical trial, while misleadingly omitting reference to more reliable, randomized controlled trials demonstrating that Provigil was ineffective for this use. No clinical trials have demonstrated a benefit of Nuvigil for treatment of MS-related fatigue.

138. MS-associated fatigue is not a medically accepted indication of Provigil or Nuvigil, and this use is therefore ineligible for reimbursement by Medicare and Medicaid. Neither Provigil nor Nuvigil has ever been approved by the FDA for the treatment of MS-associated fatigue, and none of the statutorily named compendia recommends Provigil or Nuvigil for this use. In fact, Drugdex expressly recommends *against* use of Provigil for treatment of

MS-associated fatigue, assigning it a rating of "Class III," meaning that "[t]he given test or treatment is not useful and should be avoided."

139. Drugdex's adverse recommendation reflects that controlled trials have, on the whole, failed to demonstrate the effectiveness of Provigil for treatment of MS-associated fatigue. Indeed, of the four randomized controlled trials to examine Provigil's effectiveness for this use, three have demonstrated no benefit over placebo. The first of these four included 115 patients and found no statistically significant benefit with respect to any of three measures of fatigue. B. Stankoff et al., *Modafinil for fatigue in MS: A randomized placebo-controlled double-blind study*, 64 Neurology 1139, 1141 (2005). The second, the only placebo-controlled trial to demonstrate an efficacy benefit of Provigil® for the treatment of MS-associated fatigue, was a much smaller trial that included only 21 patients. Rudiger Lange et al., *Modafinil effects in multiple sclerosis patients with fatigue*, 256 J. Neurology 645 (2009). A third trial of 121 patients again found that Provigil demonstrated no statistically significant benefit over placebo. F. Moller et al., *HAGIL (Hamburg Vigil Study): a randomized placebo-controlled double-blind study with modafinil for treatment of fatigue in patients with multiple sclerosis*, 17 Multiple Sclerosis J. 1002 (2011).

140. A recent meta-analysis incorporating the preceding clinical trials confirmed that the available evidence does not support the use of Provigil for treatment of MS-associated fatigue, finding that the results of the small Lange study were insufficient to demonstrate Provigil's effectiveness for this use when considered in context of the much larger, negative Stankoff and Moller studies. Ping Sheng et al., *Efficacy of Modafinil on Fatigue and Excessive Daytime Sleepiness Associated with Neurological Disorders: A Systematic Review and Meta-Analysis*, 8 PLOS ONE e81802, 1-2 (2013). "Meta-analyses of fatigue measured by FSS

[Fatigue Severity Scale] and MFIS [Modifed Fatigue Impact Scale] both failed to prove a beneficial effect on modafinil on fatigue associated with MS" (p=0.33 (FSS); p=0.94 (MFIS)). *Id.* at 3.

141. The conclusions of the Sheng meta-analysis were bolstered by a fourth randomized controlled trial that was published concurrently with Sheng's paper. This fourth trial included 60 patients and again found that Provigil demonstrated no benefit over placebo in treating fatigue associated with MS. Alenka Horvat Ledinek et al., *Evaluating the effects of amantadin, modafinil and acetyl-L-carnitine on fatigue in multiple sclerosis – result of a pilot randomized blind study*, 115S Clin. Neurology and Neurosurgery S86 (2013). Moreover, the Ledinek paper included not only a control group but two active control groups that examined the effectiveness of other mediations used to treat MS-associated fatigue. While Ledinek showed that Provigil was not effective for treatment of MS-associated fatigue, it showed that amantadine, the most commonly prescribed treatment for MS-associated fatigue, *was* effective. By promoting Provigil as effective for this use, Cephalon therefore not only exposed patients to the unnecessary risks of an ineffective therapy, but also deprived them of the benefit of an effective alternative.

142. To nonetheless promote Provigil after December 31, 2006 and later Nuvigil as effective for the treatment of fatigue associated with MS, Cephalon misleadingly omitted reference to the existence of well-controlled trials and instead relied on a single trial that lacked a control group. In this trial, K.W. Rammohan et al., *Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study*, 72 J. Neurology, Neurosurgery & Psychiatry 179 (2002), 72 patients received a placebo for two weeks, followed by Provigil 200 mg for two weeks, Provigil 400 mg for two weeks, and then placebo for a final

two weeks. The results showed that patients experienced a significant reduction in fatigue between the placebo run-in period and the first treatment phase. During the second Provigil phase, however, patients' fatigue reverted toward baseline and remained steady during the final placebo washout period, suggesting that any treatment effect was transient.

143. The critical shortcoming of the Rammohan trial, however, was its lack of a placebo control group, because of which the study was unable to determine whether patients' improvement was due to Provigil or to a continuing placebo effect. The randomized controlled trials confirmed this deficiency by demonstrating that use of Provigil to treat MS-associated fatigue did in fact entail a significant placebo effect. *See* Stankoff et al. at 1142 ("a major part of the benefit experienced by our patients almost certainly relates to a placebo effect"); Moller at 1004 ("Both groups showed substantial improvement in all of the fatigue scores, with significant time effects demonstrating substantial placebo effects"). This well-documented placebo effect rendered the results of the Rammohan trial meaningless.

144. Given the availability of well-controlled clinical trials that repeatedly demonstrated Provigil to be no better than placebo in treating MS-associated fatigue, Cephalon's promotion of Provigil and Nuvigil for this use based solely on the evidentially inferior Rammohan trial was fraudulent and misleading.

145. Following December 31, 2006, Cephalon's sales representatives were instructed to use misleading clinical evidence, including the Rammohan trial, as part of the company's promotion of Provigil and Nuvigil as an effective treatment of MS-associated fatigue to numerous physicians who the company knew would not use the drugs on-label. Those physicians to whom Relators Dufour and Augustine promoted Provigil after December 31, 2006 and later Nuvigil (as they had been trained to do by the company) include:

(i) Dr. Raymond J. Baddour, Neurologist, Mansfield, Ohio. As of May 2010, 25.3% of Dr. Baddour's patients were Medicare Part D recipients and 13.2% were Medicaid patients.

(ii) Dr. Brendan Bauer, Neurologist, Bellevue, Ohio. As of May 2010, 10% of Dr. Bauer's patients were Medicare Part D recipients and 5.5% were Medicaid patients.

(iii) Dr. Mark Bej, Neurologist, Sheffield Village, Ohio. As of May 2010, 30.0% of Dr. Bej's patients were Medicaid patients.

(iv) Dr. Michael J. Becker, Neurologist, Lacombe, Louisiana. Approximately 50% of Dr. Becker's patients are Medicare/Medicaid beneficiaries.

(v) Dr. Thomas A. Krefft, Neurologist, Lacombe, Louisiana. Approximately 70% of Dr. Fischer's patients are Medicare/Medicaid beneficiaries.

(vi) Dr. Marty Houser, Neurologist, Lacombe, Louisiana. Approximately 50% of Dr. Houser's patients are Medicare/Medicaid beneficiaries.

(vii) Dr. Michael Fischer, Neurologist, Lacombe, Louisiana. Approximately 40% of Dr. Fischer's patients are Medicare/Medicaid beneficiaries

146. As a direct result of Cephalon's use of misleading clinical evidence, including the Rammohan trial, all of these physicians prescribed Provigil (and later Nuvigil) to their patients, including Medicare and Medicaid beneficiaries, for the treatment of fatigue associated with MS.

147. At the time Cephalon settled with the United States in September 2008, the Criminal Information had specifically addressed the company's false and misleading misbranding of Provigil for the treatment of fatigue. As such, at all times material hereto,

Cephalon knew that its promotion of both Provigil after December 31, 2006 and later Nuvigil as safe and effective for the off-label treatment of MS fatigue was materially false.

3. Cephalon Promotes Provigil and Nuvigil for the Off-Label Adjunctive Treatment of Schizophrenia

148. Cephalon promoted Nuvigil for numerous off-label uses associated with schizophrenia, including for the adjunctive treatment of symptoms of schizophrenia itself; for treatment of fatigue and sleepiness associated with schizophrenia; and for cognitive enhancement in patients with schizophrenia. Randomized controlled trials have demonstrated Provigil and Nuvigil to be ineffective for each of these uses. However, by omitting reference to this negative clinical evidence and instead promoting Nuvigil based on smaller trials of inferior design, Cephalon succeeded in convincing physicians to prescribe Nuvigil for each of these off-label uses.

149. None of the uses referenced in the aforementioned paragraph is a medically accepted use of Provigil or Nuvigil, and each is therefore ineligible for reimbursement by Medicare and Medicaid. Drugdex expressly recommends against use of Provigil as adjunctive treatment for schizophrenia, assigning it a recommendation of "Class III," meaning that [t]he given test or treatment is not useful and should be avoided."

150. Drugdex's adverse recommendation reflects that randomized controlled trials have failed to demonstrate that Provigil and Nuvigil are effective as adjunctive treatments of schizophrenia. Nonetheless, following December 2007, Cephalon began to promote Nuvigil for the adjunctive treatment of negative symptoms of schizophrenia based on the results of a pilot study it had sponsored. That study, which was not published until 2010, failed with respect to its primary endpoint; however, Nuvigil demonstrated a benefit with respect to a secondary endpoint, the Positive and Negative Syndrome Scale (PANSS). Kane J.M. et al., *Armodafinil as*

adjunctive therapy in adults with cognitive deficits associated with schizophrenia: a 4-week, double-blind, placebo-controlled study, 71 J. Clinical Psychiatry 1475 (2010).

151. Having failed with respect to its primary endpoint, Cephalon's pilot study provided an entirely inadequate basis on which to promote Nuvigil as effective for the adjunctive treatment of schizophrenia. Secondary outcome measures are otherwise referred to as exploratory measures, and while a positive exploratory measure provides a basis for further study, it offers inadequate support for a conclusion of clinical efficacy. That held particularly true given that another randomized controlled trial, published in 2007 shortly before Cephalon received the results from its own pilot study, demonstrated no benefit for Provigil over placebo with respect to its primary outcome measure, the Scale for Assessment of Negative Symptoms ("SANS") score. Joseph M. Pierre et al., *A Randomized, Double-Blind, Placebo-Controlled trial of Modafinil for Negative Symptoms in Schizophrenia*, 68 J. Clinical Psychiatry 705 (2007).

152. Cephalon's sales representatives nevertheless leveraged the positive secondary endpoint of its pilot study to misleadingly promote to physicians that Nuvigil had demonstrated efficacy as an adjunct treatment to schizophrenia. In doing so, sales representatives misleadingly omitted that this outcome had been a secondary endpoint, as well as concealed the contrary findings of the Pierre study.

153. In response to the positive secondary endpoint of the pilot study, Cephalon initiated a follow-on trial of Nuvigil, which included the PANSS score as its primary endpoint and which the company made clear would serve as the basis for a new indication if it were positive. Rather than wait for the results, however, Cephalon's sales representatives used the trial's existence as further support for their promotion of Nuvigil's effectiveness for adjunct treatment of schizophrenia, presenting the company's receipt of the sNDA as inevitable.

154. The trial's results were in fact negative. With 285 patients, it was by far the largest trial ever conducted on the use of Nuvigil or Provigil in schizophrenia, and its failure therefore provided compelling evidence of the ineffectiveness of Nuvigil as an adjunctive treatment for schizophrenia. On June 2, 2010, Cephalon announced the results in a press release in which it also announced the discontinuation of its pursuit of the schizophrenia sNDA. *Cephalon Provides Clinical Update on Phase II Study of NUVIGIL as an Adjunctive Therapy in Adults with Schizophrenia*, PR Newswire (June 2, 2010). The study itself was not published until two years later, in 2012. John M. Kane, *Adjunctive armodafinil for negative symptoms in adults with schizophrenia: a double-blind, placebo-controlled study*, 135 Schizophrenia Research 116 (2012).

155. Even following Cephalon's receipt of the negative results of this follow-on study, however, sales representatives continued to promote Nuvigil for the adjunctive treatment of schizophrenia as they had before, based on the results of the earlier pilot study. In doing so, they fraudulently omitted disclosure of the negative trial's results, which demonstrated the falsity of their promotional claims.

156. In addition to promoting Nuvigil as adjunctive treatment for the symptoms of schizophrenia itself, sales representatives promoted Nuvigil as effective for the treatment of fatigue and sleepiness associated with schizophrenia. In support of this promotion, sales representatives primarily relied on clinical trials demonstrating Provigil and Nuvigil's effectiveness in treating excessive sleepiness associated with other conditions, which they then sought to improperly extrapolate to fatigue and sleepiness associated with schizophrenia.

157. Their promotions were also supported by a small clinical trial conducted specifically with respect to sleepiness in schizophrenia patients. The trial, published in 2002,

included 10 patients whose fatigue lessened over the course of the study; however, because the study lacked a placebo control group, it was not possible to discern whether this improvement was due to Provigil or to the placebo effect. Rosenthal and Bryant, *Benefits of adjunct modafinil in an open-label, pilot study in patients with schizophrenia*, 27 Clinical Neuropharmacology 38 (2004).

158. Subsequent trials that did include a placebo control group clearly showed Provigil and Nuvigil to be no more effective than placebo for the treatment of fatigue or sleepiness associated with schizophrenia. The first, published in 2005 shortly after Rosenthal and Bryant's study, included 24 patients randomized to receive Provigil or placebo over the course of 8 weeks. Provigil failed to demonstrate superiority to placebo. In every one of five subsequent randomized controlled trials, Provigil or Nuvigil likewise failed to demonstrate effectiveness for the treatment of schizophrenia-associated fatigue or sleepiness. Pierre et al., *supra*; O. Freudenreich et al., *Modafinil for clozapine-treated schizophrenia patients: a double-blind, placebo-controlled pilot trial*, 70 J. Clinical Psychiatry 1674 (2009); Kane et al. (2010), *supra*; William V. Bobo, *The effect of adjunctive armodafinil on cognitive performance and psychopathology in antipsychotic treated patients with schizophrenia/schizoaffective disorder*, 130 Schizophrenia Res. 106 (2011); James B. Lohr, *Modafinil improves antipsychotic-induced parkinsonism but not excessive daytime sleepiness, psychiatric symptoms or cognition in schizophrenia and schizoaffective disorder: A randomized, double-blind, placebo-controlled study*, 150 Schizophrenia Res. 289 (2013).

159. Cephalon's promotion of Nuvigil for treatment of schizophrenia-associated fatigue and sleepiness when six randomized controlled clinical trials had demonstrated Provigil

and Nuvigil to be ineffective for that use, with no parallel-group trials to the contrary, was thus blatantly fraudulent and misleading.

160. Finally, Cephalon promoted Nuvigil for use in schizophrenia patients to reduce cognitive impairment, which is often associated with schizophrenia. Although three early trials suggested that Provigil may have some benefit for this use, each of these was significantly flawed and inadequate to establish Provigil's effectiveness for this use. The first, *see* Rosenthal and Bryant, *supra*, lacked a placebo-control group and could thus not differentiate between treatment and placebo effects. The second was a crossover trial of 19 patients in which each patient received only a single dose of Provigil and a single dose of placebo. Sean A. Spence et al., *Modafinil modulates anterior cingulated function in chronic schizophrenia*, 187 Br. J. Psychiatry 55 (2005). MRIs showed a difference in brain activity; however, those on modafinil did not demonstrate improved performance on working memory tests. *Id.* at 57.

161. Better-designed, randomized controlled trials, however, have consistently demonstrated no benefit of Provigil or Nuvigil on cogitative function of patients with schizophrenia. The first of these was published in 2005, with additional negative randomized controlled trials published in 2007, 2009, 2010, 2011, and 2012. *See* Sevy et al., *supra*; Pierre et al., *supra*; Freudenreich et al., *supra*; Kane et al. (2010), *supra*; Bobo et al., *supra*; Lohr et al., *supra*; Kane et al. (2012), *supra*.

162. Among these was Cephalon's own randomized controlled pilot study, which was completed in December 2007 though not published until 2010, *see* Kane et al., *supra*, and showed no benefit of Nuvigil over placebo with respect to cognitive impairment. Cephalon's follow-on study—which was by far the largest study conducted with 285 patients, as well as the longest duration at 24 weeks—also showed no benefit to cognitive function.

163. Despite the force of contrary evidence, Cephalon's sales representatives were instructed to use misleading clinical evidence to promote Nuvigil as effective for patients suffering from various conditions associated with schizophrenia. Following December 31, 2006, the sales force was instructed to target numerous physicians who the company knew would not use the drugs on-label. Those physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil include:

(i) Dr. Jason Coe, Psychiatrist, Hammond, Louisiana. Approximately 70% of Dr. Coe's patients are Medicare/Medicaid beneficiaries.

(ii) Dr. Tim Brown, Child Psychiatrist at the Center for ADHD, Inc., Lacomb, Louisiana. Approximately 30% of Dr. Brown's patients are Medicare/Medicaid beneficiaries.

(iii) Dr. Cynthia Evans, Psychiatrist, Fremont, Ohio. As of May 2010, 7.3% of Dr. Evans' patients were Medicare Part D recipients and 6.6% were Medicaid patients.

(iv) Dr. Dorota S. Rytwinski, Psychiatrist, Fremont, Ohio. As of May 2010, 12.1% of Dr. Rytwinski's patients were Medicare Part D recipients and 10.4% were Medicaid patients.

(v) Dr. Yogesh Desai, Psychiatrist, Mansfield, Ohio. Approximately 75% of Dr. Desai's patients are Medicare/Medicaid beneficiaries.

164. That message, along with Cephalon's off-label promotional messages regarding Nuvigil's effectiveness for treatment of symptoms of schizophrenia and associated fatigue and sleepiness, succeeded in convincing physicians to prescribe Nuvigil to Medicare and Medicaid

beneficiaries for these off-label uses and thereby caused the submission of false claims to Government Programs.

4. Cephalon Promotes Provigil for the Off-Label Treatment of Fatigue in Patients Suffering from Parkinson's Disease

165. Cephalon promoted Provigil and Nuvigil as safe and effective treatments for fatigue in patients with Parkinson's disease. Numerous clinical trials, however, flatly contradicted its assertions that Provigil and Nuvigil effectively treated Parkinson's-associated fatigue.

166. Cephalon's sales representatives promoted Provigil and Nuvigil for the treatment of fatigue in Parkinson's disease patients, despite the fact that clinical trials have consistently demonstrated Provigil to be ineffective for this use. In 2005, a randomized controlled trial funded by Cephalon found that the Provigil group experienced a reduction in fatigue no greater than that in the placebo group (although it did experience a benefit with respect to excessive daytime sleepiness, a separate condition). W.G. Ondo et al., *Modafinil for daytime somnolence in Parkinson's disease: double blind, placebo controlled parallel trial*, 76 J. Neurology, Neurosurgery & Psychiatry 1636 (2005).

167. Three additional randomized controlled trials all confirmed the ineffectiveness of Provigil for treatment of Parkinson's-associated fatigue. H. Tyne et al., *A double blind placebo controlled study of modafinil for Parkinson's disease related fatigue*, 13 Parkinsonism & Related Disorders S113 (2007) (abstract); Jau-Shin Lou et al., *Using Modafinil to Treat Fatigue in Parkinson's Disease: A Double-Blind, Placebo-Controlled Pilot Study*, 32 Clinical Neuropharmacology 305 (2009); Hilary L. Tyne et al., *Modafinil for Parkinson's disease fatigue*, 257 J. Neurology 452 (2010) (funded by Cephalon).

168. A recent meta-analysis also found no difference between the efficacy of Provigil and placebo for treatment of fatigue in Parkinson's patients. Ping Sheng et al., *Efficacy of Modafinil on Fatigue and Excessive Daytime Sleepiness Associated with Neurological Disorders: A Systematic Review and Meta-Analysis*, 8 PLOS ONE e81802, 1 (2013). Despite some data suggesting a positive effect with respect to excessive daytime sleepiness, Sheng concluded that "[m]odafinil is not yet sufficient to be recommended for these medical conditions until solid data are available."

169. No clinical trials have examined the effectiveness of Nuvigil for the treatment of Parkinson's-associated fatigue.

170. Cephalon nonetheless continued to fraudulently promote Provigil and Nuvigil as effective for the treatment of fatigue in Parkinson's disease patients without disclosing the existence of convincing clinical evidence to the contrary. Instead, Cephalon's sales representatives ignored this evidence and based their promotions largely on evidence of Provigil's effectiveness at treating excessive sleepiness in other disease states, *e.g.*, obstructive sleep apnea, and sought to convince physicians that this evidence was sufficient to demonstrate Provigil and Nuvigil's effectiveness for the treatment of Parkinson's-associated fatigue.

171. Those physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil for the treatment of Parkinson's-associated fatigue include:

(i) Dr. Terence D'Souza, Neurologist, Kenner, Louisiana. Approximately 40% of Dr. D'Souza's patients are Medicare/Medicaid beneficiaries.

(ii) Dr. Michael A. Wilensky, Neurologist, Kenner, Louisiana. Approximately 40% of Dr. Wilensky's patients are Medicare/Medicaid beneficiaries.

(iii) Dr. Roy Fleming, Neurologist, Metairie, Louisiana. Approximately 35% of Dr. Fleming's patients are Medicare/Medicaid beneficiaries.

(iv) Dr. Srinivas S. Ganji, Neurologist, Covington, Louisiana. Approximately 40% of Dr. Ganji's patients are Medicare/Medicaid beneficiaries.

172. Because of Cephalon's fraudulent and misleading promotions, health care professionals prescribed Provigil and Nuvigil to Parkinson's disease patients as treatment for fatigue, which was not a medically accepted use of Provigil or Nuvigil under Medicare and Medicaid. As a result, pharmacies submitted claims to the Medicare and Medicaid programs that were ineligible for reimbursement and therefore false.

5. Cephalon Promotes Nuvigil for the Off-Label Treatment of Jet Lag

173. Jet lag is a syndrome caused by rapid transmeridien travel that entails disrupted nocturnal sleep and daytime neurocognitive impairment. Options for the treatment of jet lag include light therapy, melatonin, gradual schedule shifting, and alerting agents, *e.g.*, caffeine. *See* David E. McCarty, *Ready for takeoff? A critical review of armodafinil for modafinil for the treatment of sleepiness associated with jet lag*, 2 Nat. and Sci. Sleep 85 (2010).

174. Cephalon sought FDA approval to market Nuvigil for treatment of jet lag, and toward that end, conducted a single clinical trial designed to demonstrate Nuvigil's effectiveness for that use. That trial, which was completed in February 2009 and published in May 2010, included 427 patients with a history of jet lag symptoms who were randomized among two doses

of Nuvigil and placebo, which they took for a period of three days following travel from the US to France.

175. The trial, however, was only partially successful. While Nuvigil demonstrated superiority to placebo with regard to the first primary outcome measure on all three treatment days, it only demonstrated superiority with regard to the second outcome measure, patients' impression of their overall condition, on the first of those three days. On the second and third days, patients taking Nuvigil perceived themselves to be no better conditioned than those on placebo. *See* Russell P. Rosenberg et al., *A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study of Armodafinil for Excessive Sleepiness Associated With Jet Lag Disorder*, 85 Mayo Clinic Proc. 630 (2010).

176. On June 30, 2009, shortly after Cephalon launched Nuvigil, the company filed an sNDA for approval of Nuvigil for the treatment of excessive sleepiness associated with jet lag disorder based on the results of the Rosenberg study.

177. Even while its sNDA was pending, Cephalon promoted Nuvigil for the treatment of sleepiness associated with jet lag by informing physicians that Nuvigil had been demonstrated as effective for this use, and that Nuvigil's receipt of FDA approval for this use was imminent.

178. On March 29, 2010, however, the FDA issued Cephalon a complete response letter in which it expressed concerns about the "robustness" of the Rosenberg study's data. Statistical robustness refers to the ability of a model to produce reliable results when its variables or assumptions are altered, and a robust model remains meaningful even if certain variables or assumptions are not perfectly met. The FDA was apparently concerned that the benefits observed in the clinical trial would not persist in the real world, where Nuvigil would be used

under more varied circumstances and by a more heterogeneous patient population than it was in the trial.

179. An independent reviewer expressed analogous concerns that the treatment of jet lag is "multidimensional" and patient specific, implying that the relatively narrow patient population and regimented schedule of the Rosenberg trial may preclude an extrapolation of its results to a wider population of jet lag sufferers. McCarty, *supra*, at 90, 92.

180. Cephalon attempted to address the FDA's concerns but did so unsuccessfully. On December 27, 2010, it announced that it was abandoning its pursuit of the jet lag indication. *Cephalon Receives Complete Response Letter for NUVIGIL for the Treatment of Excessive Sleepiness Associated With Jet Lag Disorder*, PR Newswire (Dec. 27, 2010).

181. Sales representatives nonetheless continued their promotion of Nuvigil for treatment of jet lag, based both on the Rosenthal results and on assertions that Nuvigil was an effective promoter of wakefulness regardless of associated condition. Among the physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil was Dr. Kyle L. Caulfield, an internist from Hammond, Louisiana. Approximately 40% of Dr. Becker's patients are Medicare/Medicaid beneficiaries. As the direct result of the company's promotion, beginning at least in 2008 and continuing through 2011, Dr. Caulfield prescribed Nuvigil to treat his patients suffering from jet lag.

182. By ignoring and concealing the reliable clinical evidence in favor of theories and extrapolations from other disease states, Cephalon succeeded in convincing health care professionals to prescribe Nuvigil to Medicare and Medicaid beneficiaries for the treatment of jet lag and thereby caused the submission of false claims to Government Programs.

6. Cephalon Promotes Provigil and Nuvigil for Off-Label Adjunctive Treatment of Unipolar and Bipolar Depression

183. Cephalon promoted Provigil and Nuvigil off-label for the adjunctive treatment of both unipolar depression and bipolar depression. Neither of these is a medically accepted use of Provigil or Nuvigil, and Drugdex has assigned the use of Provigil for treatment of depression a "Class III" rating, meaning that [t]he given test or treatment is not useful and should be avoided."

184. Cephalon sponsored three randomized, placebo-controlled trials intended to support an sNDA for Nuvigil for adjunctive treatment of bipolar depression. The first of these three, reported in May 2012, demonstrated success, with patients in the Nuvigil group experiencing a greater reduction in depressive symptoms than those on placebo. In the second trial, however, reported in January 2013, Nuvigil failed to demonstrate a benefit over placebo. The third trial was likewise negative, and in conjunction with announcement of its results in August 2013, Cephalon discontinued its pursuit of a bipolar depression indication for Nuvigil. None of the three trials has been published.

185. With regard to unipolar depression, until 2011 all randomized controlled trials had failed to demonstrate a statistically significant treatment benefit relative to placebo in depressive symptom scores. There were three such negative trials: DeBattista C. et al., *Adjunct modafinil for the short-term treatment of fatigue and sleepiness in patients with major depressive disorder: a preliminary double-blind, placebo-controlled study*, 64 J. Clinical Psychiatry 1057 (2003); Dunlop et al., *Coadministration of modafinil and a selective serotonin reuptake inhibitor from the initiation of treatment of major depressive disorder with fatigue and sleepiness: a double-blind, placebo-controlled study*, 27 J. Clinical Psychopharmacology 614 (2007); Fava et al., *A multicenter, placebo-controlled study of modafinil augmentation in partial responders to*

selective serotonin reuptake inhibitors with persistent fatigue and sleepiness, 66 J. Clinical Psychiatry 85 (2005).

186. Even after the positive outlier trial was published in 2011, *see* Abolfazli et al., *Double-blind randomized parallel-group clinical trial of efficacy of the combination fluoxetine plus modafinil versus fluoxetine plus placebo in the treatment of major depression*, 28 Depression & Anxiety 297 (2011), the randomized controlled trials as a whole continued to weigh against Provigil's effectiveness for this use.

187. Largely due to the negativity of the available clinical evidence, Cephalon's promotion of Provigil and Nuvigil omitted reference to the randomized controlled trials and instead focused on theoretical reasons that Provigil and Nuvigil would be expected to effectively treat depression. Toward this end, Cephalon's sales representatives pointed out to physicians the strong correlation between depressive symptoms and symptoms that Provigil and Nuvigil had been shown to effectively treat in other contexts, such as sleepiness, lethargy, drowsiness, and fatigue. By treating these symptoms, sales representatives told physicians, Provigil and Nuvigil would effectively treat their patients' depression when added on to those patients' existing SSRI, SNRI, or atypical antipsychotic.

188. To further bolster their claims, sales representatives frequently pointed to the work of Stephen Stahl, a psychiatrist who had written a book proposing a psychopharmacological explanation for Provigil's potential effectiveness in treating depression. *See* Stephen Stahl, *Stahl's Essential Psychopharmacology* (2008).

189. Cephalon's use of such hypotheses as to how Provigil and Nuvigil might theoretically treat depression was plainly misleading given the existence of actual clinical evidence—namely, randomized controlled trials—that demonstrated those hypotheses to be

false. Those physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil included:

(i) Dr. Diab Almhana, Psychiatrist, Avon Lake, Ohio. Approximately 60% of Dr. Almhana's patients are Medicare/Medicaid beneficiaries.

(ii) Dr. Richard Strobach, Psychiatrist, Hammond, Louisiana. Approximately 40% of Dr. Strobach's patients are Medicare/Medicaid beneficiaries.

(iii) Dr. Cynthia Evans, Psychiatrist, Fremont, Ohio. As of May 2010, 7.3% of Dr. Evans' patients were Medicare Part D recipients and 6.6% were Medicaid patients.

190. By ignoring and concealing the reliable clinical evidence in favor of theories and extrapolations from other disease states, Cephalon succeeded in convincing health care professionals to prescribe Provigil and Nuvigil for the treatment of bipolar and unipolar depression and thereby caused the submission of false claims to Government Programs.

F. Cephalon's Off-Label Promotion Through Speaker Programs

191. Cephalon focused the off-label promotion of its drugs on promotional speaker programs, despite the heavy regulation of such programs that are 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. All presentation slides, whether provided by the pharmaceutical company or developed by the speaker, should be designed to meet these requirements.

192. A narrow exception to the "on-label" rule exists for promotional programs. Speakers may answer questions about unapproved drug uses so long as the questions posed by

the audience are unsolicited. Speakers should clearly advise the audience that the answer is outside the scope of approved labeling and that they are speaking from independent medical judgment. Questions should be answered briefly, to avoid unnecessary off-label discussion, and then the discussion should be guided back to the originally planned, on-label presentation.

193. Cephalon has understood that using influential doctors to promote its drugs off-label could be a very effective (but illegal) way to grow market share. Thus, Cephalon routinely has paid such doctors to give such promotional talks to other healthcare professionals precisely *because* they could be relied upon to *initiate* off-label discussions with members of the audience.

194. Confirming the promotional nature of these talks, Cephalon specifically instructs its sales representatives to arrange speaker programs for their large or underperforming accounts, and it only selects speakers that it knows will initiate off-label discussions.

195. The primary purpose of paid speaker programs was to use well-respected physicians to persuade their colleagues to prescribe Cephalon products, including Provigil and Nuvigil, for off-label uses. As described below, Cephalon *expected* that the speakers would initiate off-label discussions, and Cephalon's sales representatives understood that they were *not* to interrupt those discussions, nor report them to their supervisors, since doing so would limit the effectiveness of the sales pitch, thereby placing their jobs in jeopardy. That district managers attended many of these off-label presentations and remained silent, simply confirmed that it was the sales representatives' job to facilitate the off-label discussions, not prevent them, and that if they did not do their job as expected, they would be fired.

196. Further, Cephalon instructed its sales representatives to prompt off-label discussions upon completion of the original speaker presentation. For example, in 2009, Cephalon paid Dr. Tim Brown, a child psychiatrist who runs the Center for ADHD, Inc. in

Covington, Louisiana, to deliver a promotional talk. Relator Dufour was present at this event and was asked by Dr. Rene Duffourc, a psychiatrist in the greater New Orleans, Louisiana, area who was attending the event, about off-label uses of Provigil. Relator Dufour followed the training he had received from Cephalon and encouraged Dr. Duffourc to ask Dr. Brown about his experiences prescribing Provigil off-label. Dr. Duffourc asked his question, which led to a robust discussion amongst all attendees about various off-label uses.

197. In another example, post-settlement, Dr. Anil Parikh, a psychiatrist from Akron, Ohio, was paid $1,500 per program to be a promotional speaker based solely on the fact that he prescribed large quantities of Provigil and Nuvigil. Cephalon simply ignored the fact that the vast majority, if not all, of Dr. Parikh's prescriptions were written for off-label uses, including for fatigue associated with depression.

198. In all, Cephalon 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.

199. The following are examples of speakers whom Cephalon's sales force retained in order to promote its drugs off-label:

- Dr. Stephen Ellen, a psychiatrist from Nashua, New Hampshire, who served as a national speaker for Cephalon and gave dozens of Provigil and Nuvigil speaker programs, including for a wide variety of off-label uses.
- Dr. Christopher Bojrab, a psychiatrist from Carmel, Indiana, who also served as a national speaker for Cephalon. In 2011 and 2012, Cephalon paid Dr. Bojrab over $103,000 to speak on behalf of the company's products, including Provigil and Nuvigil.

Dr. Bojrab often spoke about Provigil's off-label use in the treatment of fatigue associated with depression.

- Dr. Tim Brown, a child psychiatrist who runs the Center for ADHD, Inc. in Covington, Louisiana, who was paid to participate in numerous speaker programs as a reward for prescribing Provigil and, later, Nuvigil.
- Dr. (Roger) Earl Bowie, an otolaryngologist in Covington, Louisiana, was paid to participate in numerous speaker programs as a reward for prescribing Provigil and, later, Nuvigil.

200. Cephalon was able to measure the effectiveness of its off-label promotional speaker programs through LaunchTrack—a spreadsheet that contained weekly prescribing data for each physician appearing on a sales representative's call list. LaunchTrack, which was distributed to the sales force by the company's district managers, revealed exactly how many prescriptions were being written for Provigil and Nuvigil. This data made it very easy for the company to evaluate its return on investment, both by monitoring a promotional speaker's "effectiveness" as observed through increases in the prescribing habits of the physicians who attended such programs.

201. The off-label speaker programs worked. By manipulating the promotional talks to ensure discussion of off-label uses, Cephalon was able to change physicians' prescribing behaviors. For example, Dr. Chevies Newman, an obstetrician/gynecologist from Covington, Louisiana, rarely prescribed Provigil at all, and then only for on-label purposes. However, after attending a 2008 Cephalon-sponsored speaker presentation conducted by Dr. Stephen Ellen, during which a number of off-label uses were openly discussed, Dr. Newman began writing 50 to 60 Provigil prescriptions a month primarily for the treatment of depression, an approximate

20-fold increase. The majority of these Provigil prescriptions were written for Medicare and Medicaid patients.

G. Cephalon Used "Round Table" Programs to Promote Off-Label

202. Cephalon regularly held so-called "round tables" at which it paid physicians in order to be able to promote Cephalon's drugs off-label. Although the official purpose of the round tables was to share scientific information between Cephalon and healthcare professionals with expertise in treating on-label conditions, as well as to solicit the health care professionals' advice as to the effectiveness of Cephalon's promotional messaging, in reality the round tables were thinly veiled promotional vehicles for off-label used of Provigil and Nuvigil. As discussed *infra*, the round tables also served as kickbacks to the attendees, who not only received honoraria but were provided with expensive meals.

203. Tellingly, the round tables 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 Cephalon's drugs, including for off-label uses.

204. For example, in 2009, Dr. Ellen led a physician round table funded by a Cephalon grant at La Provence, an upscale French restaurant in Lacombe, Louisiana. The other doctors in attendance were Dr. Geraldine Payne (a psychiatrist from Mandeville, Louisiana), Dr. Tim Brown (a child psychiatrist from Covington, Louisiana) and Dr. Rene Duffourc (psychiatrist from New Orleans, Louisiana). The presentation discussed the off-label uses of Provigil, including for the treatment of depression.

205. As a result of Cephalon's off-label promotion, physicians have prescribed Provigil and Nuvigil for off-label uses, resulting in the submission of false claims to Government Programs.

H. Cephalon Intentionally Minimized Safety Risks Associated with Provigil

1. False and Misleading Minimization of Safety Risks of Provigil

206. While Cephalon's off-label promotion of Provigil has focused primarily on claims of Provigil's superior efficacy for alternative treatments, Cephalon's off-label promotion has also included misleading minimization of Provigil's safety risks in order to further them impetus for physicians to prescribe Provigil for off-label uses.

207. Even after the period of covered conduct under the prior settlement, Cephalon received at least one Warning Letter 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 promote off-label uses. (The division was subsequently renamed the Office of Prescription Drug Promotion.)

208. On February 27, 2007, the FDA sent Cephalon a Warning Letter, notifying the company that a promotional piece for Provigil that it had distributed was "False or misleading because it states or suggests that Provigil is safe and effective for use in the treatment of various disorders associated with fatigue, sleepiness, or inattentiveness, when in fact, Provigil is not indicated for fatigue at all and is indicated only for specific groups of patients with excessive sleepiness as per Provigil's narrow approved indications."

209. The Warning Letter also highlights Cephalon's misbranding of Provigil as having "utility in the treatment of other neurologic and psychiatric disorders associated with fatigue,

sleepiness, or inattentiveness," including "Multiple Sclerosis Related Fatigue," "Parkinson's Disease Related Fatigue," "Chronic Fatigue Syndrome," "Fibromyalgia," "chronic pain conditions," "Attention Deficit Disorder," and "Depression."

210. The off-label uses highlighted in the FDA's Warning Letter track precisely the off-label uses Cephalon was instructing its sales force to promote in the field, which as discussed below, had a serious impact on patient health.

2. Reported Serious Adverse Events in Connection with the Use of Provigil

211. There have been numerous reported adverse events associated with the use of Provigil, including eight reported deaths. According to DrugLib.com, from October 2011 until September 2012 alone, 249 adverse event reports were made in connection with the use of Provigil. *See Provigil (Modafinil)—Side Effects & Adverse Reactions Reported to FDA, DrugLib*, http://www.druglib.com/adverse-reactions_side-effects/provigil/ (last visited Feb. 23, 2014). Of those reported events, twenty-two were categorized as "suicidal ideations," sixteen were listed as involving "mania," two were "life threatening events" and eight resulted in death, including one suicide. Recurring adverse events include reports of Stevens-Johnson Syndrome, heart palpitations, depression, paranoia, anxiety, and somnolence.

212. Six of the eight reported deaths involved incidents in which the only reported "suspect drug" administered to the patients was Provigil. *See Provigil (Modafinil)—Adverse Event Reports—All Cases—Death*, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/provigil/seriousness_ death/ (last visited Feb. 23, 2014). Specifically, on June 28, 2012, an adverse event report to the FDA explained that a male patient committed suicide, and the only reported "suspect drug" was Provigil.

213. These serious adverse events confirm that Cephalon's nationwide campaign to promote Provigil for uses not approved by the FDA has had serious consequences that directly implicate patient health.

I. Cephalon Intentionally Minimized Safety Risks Associated with Nuvigil

1. False and Misleading Minimization of Safety Risks of Nuvigil

214. The cornerstone of Cephalon's Nuvigil marketing scheme involved converting as many Provigil patients as possible to Nuvigil. Cephalon's conversion scheme deliberately ignored inherent safety issues—issues that Cephalon was aware of and intentionally misrepresented to physicians and patients alike.

215. Provigil is a mixed isomer, while Nuvigil is a monoisomer. More specifically, Nuvigil is the R-isomer of racemic modafinil. Single isomer drugs like Nuvigil are highly unpredictable in terms of patient response. Therefore, it was important for Cephalon to persuade physicians that switching their patients from Provigil to Nuvigil was safe and effective.

216. However, Cephalon knew there was no clinical data showing any clinical benefit associated with switching a patient from Provigil to Nuvigil. And Cephalon's internal business plans and training materials reflected this knowledge.

217. Central to Cephalon's challenge in its conversion strategy was the fact that there was no clinical data demonstrating bioequivalence between Provigil and Nuvigil. Cephalon knew this because it sponsored a study that was designed to support bioequivalence. In that study, a comparison was made of the pharmacokinetic ("PK") profiles of Provigil and Nuvigil at equal doses in patients with residual excessive sleepiness associated with continuous positive airway pressure-treated OSA. *See* Darwish, M. et al., *Pharmacokinetics of armodafinil and modafinil after single and multiple doses in patients with excessive sleepiness associated with*

treated obstructive sleep apnea: a randomized, open-label, crossover study, 32 Clinical Therapeutics 2074 (2010). The study concluded that, while the PK profiles of the two drugs were different, they did not meet the FDA's criteria for bioequivalence.

218. Despite these findings, Cephalon persisted, instructing its sales force to sell the Nuvigil conversion message on the basis of its pharmacokinetic data alone. The resulting marketing pitch implored physicians to use Nuvigil because it was the "longer-lasting isomer" of Provigil, implying that this fact made Nuvigil superior than Provigil. What the company failed to acknowledge, however, was that there was no data supporting the theory that Nuvigil's extended half-life provided any clinical benefit to patients. In fact, the clinical benefit of the single isomer was unknown. Meanwhile, the known safety issues, which sales representatives minimized in their sales details, were serious.

2. Reported Serious Adverse Events in Connection with the Use of Nuvigil

219. As with Provigil, there have been numerous reported adverse events associated with the use of Nuvigil, including thirteen reported deaths. According to DrugLib.com, from October 2011 until September 2012 alone, 981 adverse event reports were made in connection with the use of Nuvigil. *See Nuvigil (Armodafinil)—Side Effects & Adverse Reactions Reported to FDA*, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/nuvigil/ (last visited Feb. 23, 2014). Of those reported events, sixteen were categorized as "life threatening events" and thirteen resulted in death, including four suicides. Recurring reactions include reports of Stevens-Johnson Syndrome, heart palpitations, drug ineffectiveness, urticaria (hives), pruritus (itching), and somnolence.

220. Eleven of the thirteen reported deaths involved incidents in which the only reported "suspect drug" administered to the patients was Nuvigil. *See Nuvigil (Armodafinil—*

Adverse Event Reports—All Cases—Death, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/nuvigil/seriousness_ death/ (last visited Feb. 23, 2014). Specifically, on July 13, 2012, a physician submitted an adverse event report to the FDA explaining that a forty-two-year-old male patient committed suicide, and the only reported "suspect drug" was Nuvigil. For the three additional reported suicides, Nuvigil again was the only listed drug suspected as the cause.

221. In addition, Relator Augustine was aware of at least three instances in which patients were treated in hospital emergency rooms as the result of being switched from Provigil to Nuvigil. According to Augustine, each of the incidents was reported to Cephalon and the company was made fully aware of the hospitalizations. When Cephalon did not change its marketing campaign for Nuvigil, which continued to focus on conversion, Augustine left his employment with the company.

222. These serious adverse events confirm that Cephalon's nationwide campaign to promote Nuvigil for uses not approved by the FDA has had serious consequences that directly implicate patient health.

223. Cephalon's misleading minimization of Provigil and Nuvigil's safety profiles contributed to the effectiveness of its promotion of these drugs for off-label uses, and by doing so caused physicians to prescribe these drugs for off-label treatment and the subsequent submission of false claims to Government Programs.

J. Falsification of Prior Authorization Requests

224. Cephalon's profits from high sales of Provigil, together with Nuvigil's successful launch and increased prescribing, is due in large part to its financial relationship with prescribers and clinics. This relationship allowed Cephalon to implement its unlawful Prior Authorization

(or "PA") scheme. PA, in the context of a health care plan, including Government Program plans, refers to the process of obtaining prior approval from a private or public third-party prescription insurer about the correctness, suitability, and coverage of a service or medication that allows a physician, as well as the patient, to thus know in advance about whether a procedure, treatment, or service will be covered under his or her health plan. The PA process involves having access to patient records, completion of forms, follow-up with Government Programs, appeal letters, and related reimbursement services.

225. Faced with unfavorable formulary status and payor resistance to reimbursing for many of its drugs for off-label uses, Cephalon paid doctors to facilitate falsified prior authorization requests in order to obtain reimbursement. Cephalon has employed its non-medically trained employees to complete the reasons on the requests why patients require its particular drugs. In doing so, Defendant has not only made false statements material to false or fraudulent claims, making it liable under the False Claims Act, but it has also wantonly disregarded patient privacy protections under HIPAA.

226. Like most commercial plans, Government Program prescriptions drug plans ("PDPs") have preferred drug lists known as "formularies," which designate drugs covered by PDPs. Formularies are critical mechanisms of controlling prescription drug program costs because they incentivize patients to make efficient and economical choices when medically suitable alternatives exist. If a drug is on formulary, it will be covered when prescribed (potentially subject to restrictions to ensure that it is being properly prescribed). A formulary generally includes at least one drug in each therapeutic category.

227. In most instances, drugs that are not on formulary are not covered by Government Programs, and patients must pay the full cost themselves. However, Government Programs will

make an exception and cover a non-formulary drug if the drug is medically necessary for a particular patient, *i.e.*, if there is a reason why the on-formulary medication is not an acceptable alternative. 42 C.F.R. § 423.578. Common reasons include contraindications of the formulary medication to other medications that the patient is already taking, or prior adverse experience of the patient to the formulary-listed medication. In such cases, the prescribing physician requests a "prior authorization" (also known as an "exception request" or "coverage determination request") for the patient to receive coverage for the non-formulary drug. A legitimate, non-financial clinical reason must exist to grant to the prior authorization request.

228. Cephalon has its employees actively manipulate the prior authorization process to increase sales of its drugs, including Provigil and Nuvigil. The information included on prior authorization requests, including the information that Defendant has caused to be completed and submitted to Government Programs, has been material to the Government's decision to pay or reimburse a claim for the requested drug product.

229. The United States Office of the Inspector General for the Department of Health and Human Services ("OIG-HHS") deems free PA services highly suspect to fraud and abuse in Federal Programs, including Medicare and Medicaid. In advisory opinion No. 06-16 (issued Oct. 3, 2006) OIG found that free reimbursement services including (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, constituted remuneration and that the mere offering of such services clearly implicated the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b). In advisory opinion No. 10-04 (issued Apr. 30, 2010), 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 implicate the anti-kickback statute.

230. While Cephalon employees have promoted drugs with the aim of influencing health care professionals to prescribe its drugs to their patients, Cephalon's actions, particularly through the PA process, have a secondary and equally important impact: numerous PA requests frequently cause health plans to add the requested drug to their formularies.

231. Generally, a Pharmacy and Therapeutics ("P&T") Committee determines which drugs are included on a plan or institution's formulary and what those drugs' statuses are (*e.g.*, first or second tier). P&T Committees make formulary decisions based upon assessments of safety, efficacy, tolerability, and increasingly cost-effectiveness, and in doing so, they frequently accept or solicit input from the manufacturer of the drug under consideration. Rather than confront waves of PA requests, Government Program drug plans as well as private insurers will take into account a drug's pervasive use and place that drug on formulary, with little or no restrictions. Thus, an artificially high PA volume has the effect of clearing the formulary hurdles that Cephalon has confronted with its drugs, including Provigil and Nuvigil.

232. Although the PA process is well known to physicians, physician offices typically do not have the staff time, personnel, or the motivation to try to fight the insurers, pharmacies, benefits managers, or even the patients when it comes down to pushing for a new or different brand-name drug. Absent a compelling medical reason to start or switch a patient from one drug therapy to another, physicians will not go out of their way to switch their drug therapies (particularly when the patient has been stabilized or experienced good clinical outcomes). The PA process may also involve the provision of additional information to the health plan, appeals

of rejections, and other clerical and administrative work, all of which involve a significant expenditure of time by physician office employees.

233. Cephalon was well aware of the coverage obstacles it faced with Provigil and Nuvigil, and it therefore employed a PA strategy to overcome insurance and Government Program reluctance to reimburse these off-label prescriptions. This PA strategy provided physicians with assistance in obtaining prior authorizations and overturning coverage denials, free of charge—a service that physicians would otherwise need, that involved paying its own employees to perform.

234. Cephalon's PA scheme is an abusive practice. The authorization requested is being given for a specific medical condition, not for a one-size-fits-all diagnosis, without regard to each patient's past and current medical history, record of blood tests, or specific diagnosis. PA criteria, which vary for each *Qui Tam* State, will for example often require knowledge of a specific diagnosis, history of prior use of its drugs, or alternative therapies, and/or have the practitioner or staff complete the necessary records and authorize that the drug is being used for an FDA-approved indication. The PA scheme undertaken by Cephalon is intended to bypass these criteria, or, employ at no charge to the physician or clinic Cephalon employees to complete the PA process. Under either circumstance, Cephalon's PA scheme is an unlawful practice to violate HIPAA and create false records, or create records in reckless disregard of their accuracy, intended to be used, created and accessed by physicians and their staff—not Cephalon employees.

235. While Cephalon's official training materials have instructed sales representatives not to mention the existence of the prior authorization process and not to participate in the completion of prior authorizations, in practice sales representatives have done both. Indeed,

management has instructed sales representatives to actively manipulate the prior authorization process to increase sales of Cephalon's drugs, including Provigil and Nuvigil. At the instruction of their managers, sales representatives have (1) induced physicians and staff to complete prior authorization requests; (2) coached physicians and staff on language, often false, to include in prior authorization requests; and (3) themselves completed and submitted prior authorization requests, including by reviewing patient files.

236. Further, sales representatives have been regularly evaluated on their success at inducing staff to aid in submission of false prior authorization requests. At Cephalon, doing so has been a key part of the "total office call"— *i.e.*, a sales call that goes beyond speaking only to health care professionals but also involves office staff.

237. Specifically, sales representatives were taught to assist the physician's front office with any issues related to prior authorizations. Oftentimes, this assistance would involve ensuring that prescriptions, including especially off-label prescriptions, would get approved through the use of an "approval grid." The approval grid consisted of a spreadsheet containing information provided by National Account Managers about which drugs are covered by certain plans. If the grid revealed that a specific off-label use would not get approved by the managed care plan, including Medicare and Medicaid, sales representatives were told how to nevertheless get approval by altering the use inserted on the PA forms. Cephalon management made it known that idiopathic hypersomnia enjoyed broad approval for individuals with depression.

238. For example, Relator Dufour, carrying out his responsibilities for making a total office call, was expected to assist Dr. (Roger) Earl Bowie, an otolaryngologist in Covington, Louisiana, with prior authorizations. Relator Dufour , as he was trained to do, worked with Dr. Bowie's office manager to ensure there were no coverage issues in the prior authorizations

submitted for Provigil or Nuvigil. The information included on the prior authorization requests, including the information that Cephalon has falsified, has been material to the Government's decision to pay or reimburse claims for the requested drug product.

239. As described in this Second Amended Complaint, Cephalon's unlawful PA scheme caused physicians to prescribe, and Government Programs to pay for its drugs, including Provigil and Nuvigil.

K. Cephalon's Quotas and Bonus Programs Induced Sales to Doctors Who Do Not Prescribe Provigil or Nuvigil On-Label

240. Moreover, Cephalon's sales strategy included quota and bonus programs that motivated the sales force to sell to doctors who could not treat their patients using Provigil or Nuvigil on-label. Cephalon knew that these programs created a working environment that was conducive to promoting Provigil and Nuvigil for as many uses and as wide a patient base as possible. The quota and bonus programs, which were applied to sales representatives, district managers, regional managers, and vice presidents, were continued even after Cephalon entered into the September 2008 CIA.

241. Cephalon's quota system required the CNS sales force to detail any physician on their call lists (regardless of specialty) and awarded them with bonuses based on total sales of Provigil and Nuvigil. The only way the CNS sales force could meet the quotas that were set for them was by promoting Provigil and Nuvigil off-label.

242. The prescribers Cephalon included in its quota and bonus programs were doctors who would not normally treat patients with both Provigil and Nuvigil's limited approved indications. These doctors included psychiatrists, neurologists, pediatricians and child psychiatrists. While these doctors may have, on rare occasions, used Provigil on-label for the treatment of narcolepsy, the vast majority of these physicians only used the drugs off-label.

243. Cephalon's quota and bonus programs also influenced the selection of speakers (who were selected by the sales force, district managers, regional managers, and vice presidents) based on their ability to increase off-label sales, which would thereby boost quota and bonus scores.

244. Cephalon's strategy for promoting Provigil and Nuvigil following the settlement, which came directly from Baldino and Roche, among other senior management, was to give lip service to limiting promotion to approved indications, with the full expectation that this would be ignored by the sales force because each sales representative's individual compensation levels continued to depend on off-label sales. Senior management knew and intended that existing levels of compensation could only be maintained or increased through continued off-label selling of Provigil and Nuvigil.

245. Cephalon directly manipulated its bonus incentive program to encourage promotion of off-label sales. Even post-settlement, Cephalon built into its bonus incentive program a system designed to allow off-label sales to count toward fulfillment of sales representatives' sales quotas upon which quarterly bonuses were earned.

246. When Cephalon ended its co-promotional agreement with Takeda in 2008, the company effectively eliminated approximately 500 Takeda sales representatives from the combined Provigil sales force. But instead of decreasing the sales quotas for its remaining sales representatives who sold Provigil, Cephalon actually increased the quotas, which necessarily required the promotion of the drug for off-label sales in order to meet these sales objectives. To further encourage off-label sales, Cephalon uncapped the potential bonuses to be earned from increased sales beyond quota levels.

L. Cephalon's Use of Kickbacks To Induce Prescribing of Provigil and Nuvigil

1. Kickbacks to Paid Speakers to Prescribe and Recommend That Others Prescribe for Off-Label Use

247. Cephalon leveraged speaker fees as kickbacks to induce speakers to prescribe Provigil, and later Nuvigil, and recommend that others prescribe these drugs for off-label uses. The sales force chose the topics and the speakers, in large part based on their potential to prescribe significant quantities of Cephalon's products. As such, the speaker fees served as an improper effort to develop key opinion leaders ("KOLs") product allegiance and improve the relationships between the speakers and Cephalon.

248. Cephalon 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.

249. Cephalon's payment of kickbacks to paid speakers caused the speakers to prescribe and recommend that other physicians prescribe its products for use in off-label treatments, which in turn caused those physicians to prescribe these drugs for unapproved uses. As a result, claims for reimbursement were submitted to Government Programs. These claims were false because they were tainted by the underlying kickback, which rendered the claims ineligible for reimbursement.

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

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

251. Motivated as it is by profitability, Cephalon has been required to counter resistance by some managed care and federal programs to reimburse for Provigil and Nuvigil for certain off-label uses. Thus, Cephalon needed a mechanism to remove the reimbursement burden from physicians' shoulders. The company accomplished this objective by supplying physicians with "front office" personnel in the form of Cephalon sales representatives who were instructed to provide free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work.

252. If Medicare or Medicaid refuses to pay for the off-label use, physicians typically will prescribe Provigil or Nuvigil only if they know they will be fully reimbursed.

253. By using free reimbursement services 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.

254. Cephalon's use of free reimbursement services for off-label prescriptions 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 Provigil and Nuvigil 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.

255. Cephalon's unlawful use of free reimbursement services to aid in the misbranding of Provigil and Nuvigil, 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.

256. 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

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

257. 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.

258. 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.

259. 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.

260. 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.

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

a. Cephalon had its sales representatives call on doctors who would not normally prescribe the defendant's drugs in the course of the doctors' practice;

b. Cephalon trained its sales representatives on techniques to prompt the doctors into off-label conversations;

c. Cephalon's compensation and bonus structure encouraged off-label promotion;

d. 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;

e. Cephalon used its grants for continuing medical education to promote off-label; and

f. Cephalon sent doctors to "consultant" meetings at lavish resorts to hear the company's off-label message.

262. 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.

263. 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.

264. 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.

265. To accomplish its goal, Cepahalon 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

266. 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. In addition to the risks it shares with Actiq as an opioid, Fentora's formulation as a tablet introduced additional risks associated with the possibility that patients might accidently swallow the tablets whole, resulting in a fatal overdose.

267. 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.

268. 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).

269. 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.

270. There have been numerous reported adverse events associated with the use of Fentora, including five reported deaths. According to DrugLib.com, from October 2011 until September 2012 alone, 116 adverse event reports were made in connection with the use of Fentora. *See Fentora (Fentanyl)—Side Effects & Adverse Reactions Reported to FDA*, DrugLib, http://www.druglib.com/adverse-reactions_side-effects/fentora/ (last visited Feb. 23, 2014). Recurring adverse events include reports of increased blood pressure, suicidal ideations, intracranial aneuryism, nausea, depression, vomiting, abdominal discomfort, and somnolence.

271. In all five of the reported deaths, the *only* reported "suspect drug" administered to the patients was Fentora. *Id*. These serious adverse events confirm that Cephalon's nationwide campaign to promote Fentora for uses not approved by the FDA has had grave consequences that directly implicate patient health.

272. Cephalon's misleading minimization of Fentora's safety profile contributed to the effectiveness of its promotion of the drug for off-label uses, and by doing so caused physicians to prescribe Fentora for off-label treatment and the subsequent submission of false claims to Government Programs.

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

273. 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. Specifically, the FDA cautioned that Fentora should not be used to "treat any type of short-term pain including . . . postoperative pain." The Advisory also warned that "[h]ealthcare professionals must not directly substitute Fentora for other fentanyl medicines, including Actiq."

274. 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.

275. 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." 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.

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

276. 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.

277. 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.

278. 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 Feb. 18, 2014). 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.

279. 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.*

280. 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.

281. 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.

282. 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.

283. 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.

284. 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.*

285. 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.*

286. 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.*

287. 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.

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

288. 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:

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

289. 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 not approve Fentora for treatment of non-cancer breakthrough pain.

290. 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.

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

291. 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 (and other doctors with similar prescribing behavior) initially as an upgrade over Actiq and generally as a pain drug 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.

292. 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).

293. 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.*

F. Cephalon's Funding of Front Organizations to Assist in the Off-Label Promotion of Fentora

294. Among the strategies intentionally designed to obscure the actual sources and amounts of funding for promotional activities, Cephalon developed relationships with various "front organizations"—*i.e.*, industry-funded grassroots, consumer advocacy, research, and educational organizations whose primary goal is to promote marketing, influence regulations, or advance other industry interests.

295. Cephalon utilized non-profit organizations (such as the American Pain Foundation ("APF")) as front organizations to further its own self interest of increasing market share for the Fentora. Cephalon's funding and partnering with the APF and/or other similar organizations was designed to accomplish through a non-profit organization what Cephalon could not do on its own: giving the appearance of independent analysis and a grassroots movement encouraging FDA approval and expanding the use, including unapproved uses, for Fentora.

296. One such organization was the APF. Even though the head of the Centers for Disease Control and Prevention had declared overdoses from opioid drugs like Fentora an "epidemic," until it was dissolved in 2012, APF remained an influential champion of opiate drugs, including Fentora, describing itself as the nation's largest advocacy group for pain patients. Its message was simple: The risk of addiction is overblown, and the drugs are underused. What the nonprofit did not highlight is the money behind that message. In 2011, the foundation collected nearly 90 percent of its $5 million funding from the drug industry, including Cephalon—and closely mirrored its positions.

297. Although the foundation maintained it was sticking up for the needs of millions of suffering patients, evidence showed that it favored companies like Cephalon who have wanted to preserve access to the drugs over those who worry about their risks. Indeed, some of the foundation's board members had extensive financial ties to drugmakers, including to Cephalon.

298. The APF health advocacy harnessed the power of patient stories to sway politicians, state medical boards, judges and government health regulators, emphasizing that it represented grassroots voices. The foundation's guides for patients, journalists and policymakers played down the risks associated with opioids and exaggerated their benefits. Some of the foundation's materials on the drugs included statements that were misleading or based on scant or disputed research. And the foundation mobilized patients to send "outraged" email messages to news organizations that run stories it believes reinforce "stigmas and stereotypes" about the risks of pain medication.

299. The group's board included some patients but also doctors who were paid to speak and consult for drug companies. And one board member, Perry Fine, MD, was the lead author of a study about Fentora. Cephalon sponsored the study, and its employees were co-

authors. *See* Fine, P. G. et al. *Long-term safety and tolerability of fentanyl buccal tablet for the treatment of breakthrough pain in opioid-tolerant patients with chronic pain: an 18-month study*, 40 J. Pain and Symptom Mgmt. 747-760 (2010), *available at* http://www.sciencedirect.com /science/article/pii/S0885392410003908 (last checked on Feb. 18, 2014). The study found that the drug, Fentora, was "generally safe and well-tolerated" in non-cancer patients even though it is only approved for severe cancer pain.

300. In addition to his role as an APF board member, Fine has been a Cephalon speaker and CME advocate for the off-label use of Fentora to treat breakthrough pain. Fine also trained the Cephalon Fentora sales and marketing teams in a March 17, 2011 presentation entitled "Breakthrough Pain and Its Treatment" so that they could refine the company's off-label Fentora message.

301. However, just as the U.S. Senate Finance Committee launched its investigation in May 2012 into makers of narcotic painkillers and their relationships with doctors and advocacy groups, including APF, that have championed them, suddenly APF announced it was dissolving "due to irreparable economic circumstances."

G. Cephalon's Monies to the Federation of State Medical Boards to Fund the Model Policies for the use of Opioids to Treat Chronic Pain

302. A key part of Cephalon's scheme for off-label promotion of the Fentora was the funding for the Federation of State Medical Boards' Model Policy for the Use of Controlled Substances for the Treatment of Pain. That policy was drawn up with the help of several people (including Dr. Russell Portenoy, *see infra*) with links to opioid makers, including Cephalon. The model policy, which encourages the expansion of the use of opioids to treat all forms of pain, has been adopted in full or in part by nearly 30 state medical boards. In support of its activities,

since 1997, the Federation has received some $2 million from opioid makers including monies from Cephalon.

303. In 1998, the Federation of State Medical Boards released its first recommended policy reassuring doctors that they would not face regulatory action for prescribing even large amounts of narcotics, as long as it was in the course of medical treatment. In 2004 the group issued a revised model, for the first time calling on state medical boards to make undertreatment of pain punishable as a crime.

304. In addition, in 2007 the Federation published a book, Responsible Opioid Prescribing: A Physician's Guide written by Scott N. Fishman, M.D. (chief of pain medicine at the University of California and a frequent speaker and CME advocate for Cephalon, including for Fentora), outlining the Federation's opioid policy. Publication of the Fishman book was funded by opioid makers including by Cephalon. Over 150,000 copies of the book have been distributed by the Federation to physicians throughout the United States, touting the safety and efficacy of drugs like Fentora to treat all forms of pain, not just BTCP.

305. Fishman's own position on the use of opioids has evolved. He now believes they are overused, often in cases in which the risks outweigh the benefits. According to Fishman: "Opioids represent only a small part of the spectrum on options for mitigating pain, but they carry a disproportionate level of risk." *See* December 15, 2011 email to Propublica, http://www.propublica.org/documents/item/279033-fishman-responses-to-propublica (last visited on February 23, 2014)

306. Cephalon's funding of both the Federation's model guidelines and the Fishman book are exactly in line with the company's intended marketing plans to grow Fentora use beyond BTCP to off-label breakthrough pain.

H. The Emerging Concensus: "It was clearly the wrong thing to do."

307. At the time the FDA gave its limited approval of Fentora, on September 26, 2006, Cephalon issued a press release quoting one of its paid spokesmen, Dr. Russell Portenoy, M.D., Chairman, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, in New York City, and a principal investigator in the Fentora clinical trials: "Research on breakthrough pain conducted over the past 15 years suggested that we needed to look beyond conventional short-acting opioids and evaluate new medications that could better manage the rapid onset of this often debilitating condition. . . . The clinical trials of Fentora confirm that it is safe and effective for cancer-related breakthrough pain, and may relieve pain faster than orally ingested opioids."

308. Following the launch, Cephalon's paid thought leaders gave numerous presentations throughout the country at medical conferences and elsewhere touting Fentora not just for the treatment of BTCP in opioid tolerant patients, but for the much broader (and off-label) treatment of all forms of breakthrough pain. Portenoy himself was a speaker for Cephalon, and was lead author of a paper discussing the use of Fentora to treat breakthrough pain. Portenoy et al., *Fentanyl buccal tablet (FBT) for relief of breakthrough pain in opioid-treated patients with chronic low back pain: a randomized, placebo-controlled study*, 23 Current Medical Research and Opinion 223-233 (2007), *available at* http://informahealthcare.com /doi/abs/10.1185/030079906x162818 (last checked on Feb. 23, 2014).

309. Dr. Portenoy has long been one of the most influential voices urging the use of opioids for patients with chronic noncancer pain, arguing that these constitute a safe and effective therapy. For years he has advocated for the long-term use of drugs like Fentora as safe for the treatment of all forms of pain, not just BTCP.

310. However, amid growing concerns of an "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," the Senate Finance Committee subpoenaed Dr. Portenoy and a number of other physicians, including Drs. Fine and Fishman, in May of 2012, as part of an investigation into their financial ties with pharmaceutical makers and how this influenced their advocacy for opiate drugs, including Fentora. Among the areas of the Committee's inquiry were also the financial ties drug companies had to pain advocacy groups American Academy of Pain Medicine (AAPM), American Pain Foundation (APF), American Pain Society (APS), Center for Practical Bioethics, and the Pain & Policy Studies Group. Cephalon has long been a supporter of many of these advocacy groups.

311. In a December 17, 2012 Wall Street Journal article, Dr. Portenoy admitted that they had gone too far in promoting opiates for the treatment of pain. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did. . . . We didn't know then what we know now." *See* T. Caten and E. Perez, "A Pain-Drug Champion has second thoughts. The Wall Street Journal Online December 17, 2012, http://online.wsj.com/news/articles/SB10001424127887324478304578173342657044604 (last checked on February 23, 2014). According to the article:

> Dr. Portenoy said it was "quite scary" to think how the growth in opioid prescribing driven by people like him had contributed to soaring rates of addiction and overdose deaths. "Clearly, if I had an inkling of what I know now then, I wouldn't have spoken in the way that I spoke. It was clearly the wrong thing to do. . . ."

According to one colleague of Dr. Portenoy's, Steven Passik, "their message wasn't based on scientific evidence so much as a zeal to improve patients' lives. It had all the makings of a

religious movement at the time. It had that kind of a spirit to it." Portenoy now admits there is little scientific evidence that opioid drugs are safe and effective for long-term use: "Data about the effectiveness of opioids does not exist. Do they work for five years, 10 years, 20 years? We're at the level of anecdote."

I. The Off-Label Promotional Scheme for Fentora

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

312. Cephalon launched Fentora on October 1, 2006—and simultaneously began its off-label promotional plan. In doing so, Cephalon nearly doubled the number of sales representatives selling Fentora by taking the approximately 80 former Actiq sales representatives and adding approximately another 70 general pain sales representatives. Although the market for Fentora's only on-label treatment—breakthrough pain for opioid-tolerant cancer patients—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 pain specialists and other doctors who treat a wide array of pain conditions—although BTCP is generally not among them.

313. 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.

314. Nonetheless, in light of the settlement and CIA involving Actiq, Cephalon was cautious to avoid the appearance of promoting off-label sales. Cephalon concealed its off-label promotional practices by avoiding all overt references to off-label marketing from its Fentora

promotional materials. Although promotional documents provided to Cephalon's Pain sales force appeared to emphasize approved indications for use and monitor sales in those categories, Cephalon made these changes with the expectation that they would be ignored by sales representatives. In fact, Cephalon continued to pressure its Pain sales force with ever-increasing sales quotas with the knowledge that this would require its sales representatives to market off-label uses of Fentora to non-oncology doctors in order to reach the demanded level of sales. Each quarter, Fentora sales representatives would experience a 30% increase on their previous sales quota; the failure to make quota resulted in a penalty increase the following quota (*e.g.*, instead of a 30% increase, a 35% increase).

315. Cephalon's primary marketing goal during this period was to switch as many Actiq-prescribing physicians as possible from Actiq—which was off-patent and would soon face generic equivalents—to Fentora—which had no generic equivalent against which to compete, and would be far more profitable as a brand-name drug. Indeed, in promoting Fentora Cephalon directed its Pain sales force to continue targeting the same Actiq-prescribing physicians that had already been coached in prescribing the drug off-label. The mere fact that a doctor had previously prescribed Actiq—regardless of the physician's specialty or whether he or she ever treated cancer patients or used the drug for on-label purposes—was enough to cause Cephalon to require sales representatives to call on that doctor to sell Fentora.

316. Cephalon's basic message to doctors 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*. In fact, Cephalon sales representatives were initially incorrectly trained to advise physicians to write prescriptions for

Fentora, as they had Actiq (*i.e.*, the same fentanyl dosages) on the basis that Fentora was as good or better than Actiq. This instruction, however, proved dangerous and may have caused several patient deaths, because Fentora's delivery method is more efficient than that of its predecessor in entering the bloodstream, and such incorrect advice could lead to an increased risk of overdosing or death for patients prescribed Fentora.

317. The plan to launch Fentora by cannibalizing sales of Actiq was a success, and on February 12, 2007, only five months after the launch, then-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 Feb. 24, 2014). 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.

318. 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).

319. 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.*

320. 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."

321. 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. Fentora 2006 Marketing Plan Focuses on Sales of Off-Label Non-Cancer Breakthrough Pain

322. 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 "Marketing Plan 2006" clearly reflects that Cephalon sought to build on its off-label promotion of Actiq as the basis for its promotion of Fentora. Cephalon sought to convert doctors, 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.

323. The document's Executive Summary (which, astonishingly, does not even mention cancer pain) sets the tone of the document and makes unequivocally clear that the focus is on off-label promotion for the treatment of all forms of pain. The "Market Drivers" were:

- "Increase in the number of chronic pain patients continues to drive prescriptions";
- "Aggressive treatment of pain continues to drive market value despite introduction of generics…"; and
- "Pain specialists remain most productive speciality segment while PCP's [primary care physicians] drive shares…"

The "Market Threats" threats were:

- "Fear of abuse, addicition, & diversion persists among all specialties"; and
- "Treatment Guidelines (regarding BTP) are still evolving."

Again, breakthrough cancer pain did not warrant even a mention.

324. Indeed, in summarizing the relevant marketing strategy for Fentora, Cephalon's Year 1 Commercial Vision expressly identified that the objective was to "convert ACTIQ loyalists to FEBT [fentanyl effervescent buccal tablet] adopters, with the goal of switching ACTIQ patients and driving new patient starts with this existing prescribing base." Given that

the vast majority of prescribers of Actiq were pain specialists who did not prescribe Actiq for its on-label use to treat BTCP (or, if they did, it was a negligible part of their practice), Cephalon's goal is to maintain market share for off-label use.

325. The plan notes that "the most productive physician segment for ACTIQ is . . . Pain [Medicine Doctors]" who wrote 68 prescriptions for Actiq per physician in 2004, and that "pain specialists remain [the] most productive specialty segment" for marketing Fentora. Cephalon's Marketing Plan makes clear it sought to duplicate Actiq's success with Fentora.

326. Cephalon also clearly roadmaps its far-reaching and comprehensive Fentora marketing strategy in the 2006 Marketing Plan to not only duplicate and continue the Actiq market but surpass it. Rather than scratching any mention of Actiq, given the fact that Actiq was virtually only used off-label, or rather than qualifying its discussion of Actiq, the document reflects the company's plan to tout Fentora as a better version of Actiq for the same off-label purposes. According to the marketing plan, "Preliminary Supporting Messages" (which were "in development") included references to the fact that Fentora had "rapid onset pain relief for BTP"—again, no mention of breakthrough *cancer* pain—and "discreet dosing administration compared to ACTIQ."

327. Further, Cephalon identifies two groups as being crucial to Fentora's success, Key Opinion Leaders ("KOLs") and Managed Care/Third-Party Payers ("TPPs") — groups that were to be the targets for Cephalon's two key off-label promotional strategies, respectively, the Fentora speaker programs and the Fentora reimbursement program.

328. Recognizing that "the number 1 reason a physician/HCP [healthcare provider] changes prescribing habits is peer-to-peer influence," Cephalon identified and trained KOLs to promote off-label use of Fentora. These identified healthcare providers and academics would

participate in "publications, medical education," and provide other doctors with information regarding the "appropriate use of FEBT for BTP." As described in greater detail below, these KOLs would continue to be utilized by Cephalon in a variety of ways described herein: drafting journal supplements, conducting clinical studies, publishing articles, and participating in Cephalon's Fentora speaker programs.

329. Cephalon also recognized that managed care plans "continually seek to control costs by driving utilization to generics or lower cost branded products" by utilizing "tiered co-pays, prior authorization, [and] step edits." For this reason, Cephalon proposed that a "comprehensive managed markets plan will need to be executed in order to achieve favorable reimbursement status" for Fentora in the "highly genericized market" for chronic pain. In accordance with this plan, as described below, Cephalon trained its sales force to handle managed care (including state Medicaid plans, as well as managed Medicare and Medicaid plans) prior authorization requests and directed its sales force to assist doctor's offices with obtaining necessary Fentora reimbursements.

330. Overall, the 2006 Cephalon Marketing Plan is striking in its near exclusive discussion of breakthrough pain, with only a perfunctory, occasional reference to cancer patients. For example, the document discusses a "patient database" to "capture both ACTIQ & cancer patient names," thus implicitly acknowledging the non-overlap between the populations, and then going on to concede that the "target audiences" of the database were "ACTIQ patients." As shown below, the focus on reaching "ACTIQ patients"—*i.e.*, off-label patients—was successful.

3. Fentora 2007 Marketing Plan Focuses on Sales of Off-Label Non-Cancer Breakthrough Pain

331. 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

"Marketing Plan 2007" an internal company document that sets forth the marketing goals for the drug. The marketing plan outlines Cephalon's strategy and tactics for promoting Fentora during 2007 and beyond. While the document reflects some growing recognition of the company's need to be careful in its explicit off-label messaging, the thrust is the same as the earlier plan, as reflected in the bottom-line comment in the "three-year strategy": "What FENTORA Should Be: The optimal solution for BTP."

332. Moving forward, Cephalon planned to continue pursuing a strategy of leveraging the opioid pain market to drive sales of Fentora, despite the knowledge that Fentora's only approved usage was for BTCP. The Fentora Marketing Plan 2007 makes clear that Cephalon sought to expand usage well beyond BTCP in the same manner as Actiq, by focusing on non-cancer breakthrough pain (BTP). The plan sets forth a goal of "continu[ing] to establish BTP as a distinct clinical problem" as part of "BTP disease awareness campaign." As part of a three-year strategy, Cephalon sought to position Fentora "as the optimal therapy for BTP vs Oxy IR and other [short-acting opioids] SAOs," clearly identifying its competition as general opioids, despite Fentora's limited indication for BTCP.

333. In promoting "BTP as a distinct clinical problem" from BTCP, Cephalon continued to focus on non-oncologists. Cephalon primarily targeted pain specialists and primary care physicians (PCPs) as market "Growth Drivers" based on the company's research that "[p]ain [s]pecialists are more aggressive in treating chronic pain" and that "PCPs . . . continue to drive the majority of opioid [total prescriptions] TRx volume." These objectives stand in stark contrast to the perfunctory extent to which Cephalon would be targeting oncologists, or even limited its targeting to non-oncologists to narrow on-label use of this dangerous drug.

334. The Fentora Marketing Plan 2007 contains repeated references to marketing Fentora as a drug for use in treating BTP in *chronic pain patients*, with no reference to its limited indication for use in opioid-tolerant cancer patients — its only approved use. Cephalon identified as a "Growth Driver" the fact that "[a]ging baby boomers and growing US population will increase the size of the chronic pain patient population," signaling that the company planned to expand and continue promoting Fentora for off-label use in non-cancer patients. Likewise, the "Three Year Strategy" for marketing Fentora sets forth a goal of ensuring that "[r]outine use of FENTORA [is used] to treat BTP in a broader population," yet again emphasizing the centrality of this primarily off-label demographic in Cephalon's promotion strategy for Fentora.

335. The 2007 Marketing Plan also set forth the "Managed Care Tactics" Cephalon would use to ensure that Fentora will be fully reimbursed by Medicare, Medicaid, and other third-party payers. Office manager "advisory boards," training workshops, and "luncheon programs" are described as providing "specific training and appropriate tools to reduce PA [prior authorization] resubmission and rejection rates." These office manager and staff training programs appear to be associated with Fentora's reimbursement program, the goal of which was to encourage the continued off-label prescribing of Fentora by ensuring that patients received full reimbursement for their off-label prescriptions. Providing doctors' office managers and staff with "training and appropriate tools" to push through necessary prior authorization supports the Fentora reimbursement program's goals.

336. The 2007 Marketing Plan also reflects Cephalon's clear recognition of the centrality promotional speakers had in promoting off-label use, dedicating just over 20% of its entire promotional budget to field driven speaker programs.

4. Cephalon's Internal Sales & Marketing Audit Warns of Marketing Irregularities

337. Cephalon's implementation of the goals and strategies set forth in its 2006 and 2007 Marketing Plans to promote Fentora off-label is confirmed in its December 2008 Internal Audit of Sales & Marketing Compliance Programs. This internal company document is a confidential document identifying weaknesses in Cephalon's compliance with its own internal compliance procedures that were implemented subsequent to the CIA. Nonetheless, as is the case with all Cephalon high-level management documents post-settlement, the audit attempts to sanitize its descriptions of Cephalon's non-compliant activities and avoid an express discussion of the company's off-label schemes.

338. The audit reviewed strategies relating to the launch and the subsequent sales and promotional activities undertaken with relation to Fentora. The key areas of review concerned Cephalon Speaker Programs ("CPSs"), and sales force activities such as "call planning and physician targeting."

339. The internal audit team conducted "[r]eal-time review of Cephalon's sponsored promotional Speaker Programs" and concluded that there were several areas that required greater compliance with the CIA.

340. The auditors noted that Cephalon had failed to institute a "Fair Market Value (FMV) methodology . . . to control and benchmark fee-for-service arrangements with HCPs." This failure to provide and use a formal fee schedule is in violation of guidance provided by the OIG to pharmaceutical companies, because it gives "the appearance of offering inducements to change prescribing behavior." The report correctly warned that "Cephalon could potentially be at risk for not embracing OIG guidance." Indeed, Cephalon should have been fully aware that compensation between pharmaceutical companies and doctors may implicate the Federal Anti-

Kickback Act ("AKA")—if compensation for speaker fees or other services exceeds their fair market value. As part of the CIA, Cephalon specifically agreed to ensure its "Promotional and Product Services" programs in compliance with the AKA and other laws. Its identified failure to do so here was in violation of the CIA.

341. The auditors also noted that the Cephalon Speaker Programs lacked an "impartial review process" such that "non-compliant CPS programs may be taking place." The report also noted that, without such a tracking mechanism, it would be "possible that an HCP [health care professional] though corrected may continue to not conform to Cephalon policies." The internal audit attempts to not expressly name the "non-compliant" activity at issue here, but it is evident that it is a clear reference to violations of requirements that company sponsored presentations not promote unsolicited off-label use. Notably, as discussed below, Cephalon ensured the programs would be all about off-label use by using virtually zero percent oncologist speakers, and instead regularly paying pain doctors, neurologists, anesthesiologists, and others to instead do its bidding. Cephalon thus avoided tracking off-label discussions because it had no intent to punish doctors for discussing use beyond the FDA-approved labeling – particularly, because it deliberately planned its CPSs to *encourage* such discussions. Cephalon also avoided tracking CSP non-compliance in order to maintain plausible deniability regarding the content of the Fentora speaker programs. Without such statistics, Cephalon could purport to shift the blame from its own well orchestrated marketing and promotional policies — which effectively demanded off-label discussion during CSPs — onto its sales representatives and hired physician speakers.

342. The off-label tactics discussed in Fentora's marketing plans also did not escape the audit's review. Specifically, the report identified as problematic Cephalon's plans "targeting

'high opioid' prescribers without qualifying comments regarding breakthrough cancer pain," because this language "may give regulators the incorrect appearance that off-label promotion is occurring." This internal warning to management makes clear that Cephalon was wholly aware of the difference between BTCP — the only approved on-label indication for Fentora — and BTP — the off-label use it promoted through its marketing and promotional materials. Regardless of this warning, Cephalon continued to discuss and actively promote Fentora for off-label non-cancer breakthrough pain.

343. The audit also identified the targeting of prescribers as another area for improvement. The report noted that "[c]all universes are not monitored to verify that previously qualified prescribers remain appropriate," such that "inappropriate prescribers" may remain in call universes. In the context of Fentora, the auditors are clearly referring to Cephalon's blatant policy of creating Fentora's physician call lists using the *same* doctors who had previously prescribed Actiq. Despite the coded language of the internal review, "inappropriate prescribers" are the same pain doctors who had prescribed Actiq off-label—physicians to whom Cephalon had expressly directed its pain sales force to target in its 2006 and 2007 Marketing Plans.

5. Cephalon Targets Physicians Who Treated Negligible Numbers, If Any, Cancer Patients

344. In accordance with its Marketing Plans, Cephalon continued to market Fentora off-label for pain applications well-beyond the narrow scope of Fentora's FDA marketing approval for BTCP, or its approved uses found in the statutorily named Compendia.

345. Marketing executives would direct the Fentora sales force to "stay out of oncology, and go directly to pain," and focus its targeting on doctors who were high-prescribers of opioids and narcotics such as pain specialists. Indeed, all the physician targeting lists focused

on the level of opioid prescribing by the doctor. There was no instruction to call on doctors who were engaged in treating cancer patients.

346. These marketing executives included Andy Pyfer, a senior marketing director, and Mark Napoletano, an associate marketing director. This instruction was mirrored by Sales managers, including a regional sales director, Chuck DeWildt who would instruct sales representatives to focus on non-oncology doctors.

347. In addition to pain specialists, Fentora is marketed off-label to a larger group of doctors, including psychiatry or rehabilitation specialists, anesthesiologists, internal medicine, general practitioners, family medicine practitioners, and other primary care physicians who have prescribing patterns similar to those of pain specialists.

348. Many of these physicians who did not treat breakthrough cancer pain may lack the experience with opioids intended for opioid-tolerant patients necessary to fully appreciate the dangers of Fentora as compared to other pain medications. Cephalon markets Fentora off-label primarily through direct calls by sales representatives on these non-oncologists, while visiting oncologists — who actually see patients with breakthrough cancer pain — only approximately 20% of the time. An internal presentation to Cephalon management in 2009 documented that 44% of Fentora prescriptions were written by pain doctors, 20% by PCPs, 14% by nurse practitioners and physician's assistants, 12% by "other" healthcare professionals, 6% by neurologists, and that oncologists accounted for only 4% of all Fentora prescriptions.

349. Despite Fentora's limited approval for only breakthrough cancer pain, Cephalon's Pain sales force aggressively promoted the drug for off-label use, particularly for non-cancer breakthrough pain. In addition, Fentora was also marketed to physicians known by Cephalon sales management to use the drug off-label in a pre- or perioperative setting, such as for

preoperative sedation or as an adjunct to anesthesia. There are no directions or dosage recommendations for the use of Fentora in this perioperative setting. In fact, the use of Fentora in perioperative setting is contraindicated for use for such short-term pain by the FDA for several reasons as set forth in the Black Box Warning on the label, which specifically states that "[d]ue to the risk of fatal respiratory depression, FENTORA is contraindicated in opioid non-tolerant patients . . . [and] postoperative pain."

350. As a result of Cephalon's off-label promotional activities, physicians prescribed and submitted false claims for reimbursement of Fentora for off-label use to Government Programs. Cephalon's own marketing documents demonstrate that more than 80% of Fentora sales are associated with off-label uses.

351. The following are examples of some of the physicians induced by Cephalon's pain sales force to prescribe Fentora off-label:

- Dr. James Cole, a physical medicine and rehabilitation medicine specialist from Albany, New York, who does not treat cancer patients.
- Dr. Jacob Abraham, an anesthesiologist from Hot Springs, Arkansas, who used Fentora perioperatively.
- Dr. Gary Wright, a anesthesiologist from Indianapolis, Indiana, who uses the drug for conscious sedation, and does not treat cancer patients.
- Dr. Daniel Bennett, an anesthesiologist and pain specialist from Golden, Colorado, primarily prescribed Fentora off-label.
- Dr. Howard Heit, an internist and gastroenterologist from Fairfax, Virginia primarily prescribed Fentora off-label.
- Dr. Stephen Landy, a neurologist from Cordova, Tennessee, described below.

6. Off-Label Promotion of Fentora Through Speaker Programs

352. Beginning after the Fentora launch in 2006, Cephalon's Pain sales force set up hundreds of speaker programs for healthcare professionals during 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. Fentora had nearly two hundred speakers, that were paid an honoraria of $1,500 to $2,000 per event, and could give two to three events per day, with some speakers earning tens of thousands of dollars per year. As such, the speaker monies were an improper effort to develop KOL product allegiance and improve the relationships between the speakers and Cephalon.

353. For example, as he was directed to do by his manager, former Cephalon sales manager, Alec Burlakoff, organized numerous speaker programs in the Florida region in order to promote off-label sales of Fentora for the treatment of breakthrough pain.

354. Cephalon provided the selected physician speakers with training and a Cephalon-approved Fentora promotional speaker slide deck. Speakers, however, were permitted to create and add their own slides into the presentation. These slides would discuss the doctor's personal experience with prescribing Fentora, which included discussions of how they used Fentora off-label in their own practice. Although sales representatives and sales managers were aware that these slides promoted prohibited off-label prescribing, Cephalon turned a blind eye, believing apparently that speakers were, as a practical matter, less likely to get caught, since attending physicians would be more likely to report an objectionable off-label message delivered by a sales representative than one delivered by a physician colleague.

355. As was the case with its Provigil and Nuvigil speaker programs, Cephalon did not enforce the legal requirements that paid physician speakers limit their promotional presentations to on-label uses (as was required of Cephalon's sales representatives). Cephalon instructed its Fentora sales force that if doctors were speaking to one another—even a Cephalon-selected and paid speaker—off-label discussions were the intended and acceptable outcome.

356. Indeed, Cephalon *expected* that the speakers would initiate off-label discussions, and Cephalon's sales representatives understood that they were *not* to interrupt those discussions, or report them to their supervisors, or prevent the use of speaker-created slides concerning off-label use since doing so would limit the effectiveness of the underlying sales pitch, thereby placing their jobs in jeopardy. There was no compliance review of the numerous speaker events that would even permit such oversight of off-label content.

357. Cephalon retained numerous physicians as Fentora speakers who do not generally (or at all) treat breakthrough cancer pain. For example, Cephalon retained internal medicine, general practitioners, family medicine practitioners, and other primary care physicians who have prescribing patterns similar to those of pain specialists.

358. The following are examples of some of the physicians retained by Cephalon's pain sales force as speakers in order to promote Fentora off-label:

- Dr. Stephen Landy, a neurologist from Cordova, Tennessee gave Fentora speaker programs and was paid $98,600 in honoraria in 2009, and $90,979 in speaking and travel fees in 2010. As a neurologist, Dr. Landy did not geneally treat cancer patients.

- Dr. Donald R. Taylor, an anesthesiologist from Marietta, Georgia gave Fentora speaker programs and was paid $142,050 in honoraria in 2009. He primarily prescribed Fentora off-label.
- Dr. Wayne Anderson, a neurologist from San Francisco, California gave some 37 Fentora speaker programs for Cephalon in 2009 and 2010, and was paid $173,950. He runs a neurology, pain, headache clinic and is not likely to treat cancer patients.
- Dr. Paul Brown, an internal medicine doctor and rheumatologist gave some 20 Fentora speaker programs for Cephalon in 2009 and 2010, and was paid $99,800. He is not likely to treat cancer patients.
- Dr. James McMillen, an internal medicine doctor and rheumatologist gave some 19 Fentora speaker programs for Cephalon in 2009 and 2010, and was paid $126,000. He is not likely to treat cancer patients.

359. 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.

7. Off-Label Promotion of Fentora Through Journal Supplements

360. 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.

361. 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.

362. The supplement was prepared by McMahon Publishing, 545 West 45th Street, New York, New York 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."

363. 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.

364. 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 only to breakthrough cancer pain. Moreover, Narayana fails to point out to readers that the FDA had specifically rejected Cephalon's request to expand the label to non-cancer breakthrough pain.

365. 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.

8. Off-Label Promotion Through Preceptorships

366. In addition to providing high-prescribers of Fentora with speaker honoraria, Cephalon, during the first year of promoting Fentora, provided doctors with a financial inducement known as "preceptorships."

367. Preceptorships served as another means by which Cephalon concealed its payment of kickbacks to health care professionals. In a preceptorship, a Cephalon sales representative paid a high-volume prescriber— *i.e.*, a doctor who prescribed a large quantity of Fentora, from $500 up to $1,000 to permit the sales representative to follow the health care professional during patient examinations for all or part of a day. In theory, preceptorships provided sales representatives with insight into how physicians decided which drugs to prescribe. In practice, sales representatives rarely stayed with physicians for more than a short time, and the preceptorships were a thinly veiled means of funneling cash to physicians who Cephalon expected to reciprocate by writing more prescriptions for Fentora, including for off-label uses.

368. Preceptorship payments were made by sales representatives to physicians for the putative "educational" purpose of permitting the sales representatives to observe the physician's practice for a 2-4 hour period, so that the sales representative could better understand how the physician evaluated, diagnosed, and treated patients. Such "shadowing," however, in reality was

intended to buy access to top-level targets—those physicians who were identified based on their high level of prescribing of pain medication—and to reward already high-prescribers of Fentora with financial rewards.

9. Cephalon Sponsored Clinical Studies to Support Off-Label Prescribing of Fentora

369. Cephalon also funded and sponsored a variety of clinical studies and journal articles to promote the off-label use of Fentora. During the Fentora launch and through the first year of sales, these clinical studies were presented by the marketing division to the Fentora sales force at national sales meetings and trainings to suggest that the FDA was moving towards approving certain off-label uses such as for non-cancer breakthrough pain, migraine pain, and general chronic pain. In reality, these studies were provided to sales representatives to encourage them to promote Fentora for off-label use to physicians on the misunderstanding that these off-label uses would shortly be approved by the FDA.

370. Some of the studies that were shared with the Fentora sales force included the Dr. Russell Portenoy article previously mentioned and excerpts from the book "Responsible Opioid Prescribing: A Physician's Guide written by Scott N. Fishman, M.D.

371. Although these clinical studies were provided as reference materials to the sales force, during this period Cephalon did not institute any guidelines or restrictions on their use as promotional materials to be used on sales calls with physicians. Thus, sales representatives would discuss these off-label clinical studies and articles with physicians to encourage or increase off-label prescribing.

372. A review of the clinical studies and journal articles discussing the use of Fentora in non-cancer breakthrough pain reveals that Cephalon is either directly or indirectly involved in nearly all of those publications, either by sponsoring the study, "supporting" the writing of the

article, or having the paper authored or the study conducted by a Cephalon employee or paid consultant. Thus, despite the overwhelming risk of addiction that even limited on-label BTCP use of Fentora presented, Cephalon actively set out to build a consensus around the notion its marketing plans had set out to achieve, use of Fentora for all forms of breakthrough pain.

373. For example, one non-peer reviewed article, concluded after a review of clinical studies that Fentora should be used in opioid tolerant patients for breakthrough pain regardless of whether the patient had cancer versus noncancerous reasons for pain—directly in opposition to the FDA and Drug Compendia's indicated uses. The article was funded by Cephalon, authored in part by two Cephalon employees (Drs. Messina and Darwish), and medically reviewed by another Cephalon employee (Dr. Narayana). *See* Darwish, M. et al., *Fentanyl buccal tablet for the treatment of breakthrough pain: pharmacokinetics of buccal mucosa delivery and clinical efficacy*, Perspectives in Medicinal Chemistry, 4, 11 (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901636/pdf/pmc-2010-011.pdf (last visited Feb. 19, 2014).

374. A clinical study evaluating the effect of Fentora in opioid tolerant *noncancer patients* for breakthrough pain concluded that the drug showed clinically important analgesic effects and was generally well tolerated even for long-term treatment. The primary author, Dr. Srinivas Nalamachu, a physical medicine and rehabilitation specialist from Overland Park, Kansas, had been paid over $440,000 dollars by Cephalon in speaking fees, consulting fees, travel and meals between 2009-2011. The other two authors listed on the study, Drs. Narayana and Janka, were Cephalon employees. *See* Srinivas R. Nalamachu, Arvind Narayana & L. Janka, *Long-term dosing, safety, and tolerability of fentanyl buccal tablet in the management of noncancer-related breakthrough pain in opioid-tolerant patients*, Current Medical Research &

Opinion, 27(4), 751-760 (2011), *available at* http://informahealthcare.com/doi/abs /10.1185/03007995.2011.554808 (last visited Feb. 19, 2014).

375. In addition to promoting the off-label use of Fentora for non-cancer breakthrough pain, Cephalon also attempted to promote the use of the drug to alleviate certain psychiatric symptoms in opioid-tolerant patients with chronic pain or breakthrough pain. *See* Lynn R. Webster, John Messina, Frank Xie, & Srinivas Nalamachu, *Effect of fentanyl buccal tablet on pain-related anxiety: a 4-week open-label study among opioid-tolerant patients with chronic and breakthrough pain*, 7 Journal of Opioid Management, 297-308 (2010). Although the clinical study concluded that Fentora "did not reduce anxiety to a clinically meaningful extent," it clearly demonstrates Cephalon's attempt to broaden the market for off-label uses of Fentora well beyond the boundaries of indicated usage approved by the FDA. Of the authors of the clinical study, two (Drs. Messina and Xie) were Cephalon employees. As mentioned above, Dr. Nalamachu is a paid Cephalon consultant and Dr. Lynn Webster is also a paid consultant, having earned over $18,000 in 2009-2010 for speaking fees, consulting, and research.

J. Cephalon Offers Kickbacks to Customers to Induce Off-Label Prescriptions of Fentora

376. Cephalon has developed and manipulated its own 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

377. 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 Government Programs.

378. 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.

379. 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.

380. 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

381. 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.

382. Cephalon provided customized reimbursement support services to doctors and their office managers, including a Fentora Hotline. Cephalon has intervened on behalf of healthcare providers seeking to be reimbursed for off-label Fentora prescriptions.

383. 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).

384. But for the illegal kickbacks, Government Programs would not have paid for these false claims for off-label uses. Cephalon'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 Government Programs, 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

385. In order to execute its off-label promotion and kickback scheme for Provigil, Nuvigil and Fentora, Cephalon 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").

386. 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

387. 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.

388. 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)."

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

390. 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.

391. 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."

392. 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.

393. 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).

394. 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.

395. 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.

396. 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

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

398. Cephalon's promotion of Provigil, Nuvigil and Fentora for off-label uses constituted a violation of the company's CIA and is a remarkable admission that Cephalon does not take seriously its obligations under the prior plea agreement.

399. 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.

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

400. 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 Provigil, Nuvigil and Fentora.

401. 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."

402. Cephalon violated the express terms of the CIA each time it failed to properly report to OIG the financial inducements the company paid to physicians, 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

403. Cephalon's off-label promotional schemes served their intended purpose, as they induced doctors to write off-label prescriptions for Provigil, Nuvigil 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.

404. Due in part to Cephalon's illegal conduct, Provigil, Nuvigil 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

405. Cephalon provided health care professionals with remuneration related to CME programs, promotional speaker programs, and round table presentations, 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 analogs.

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

407. As described in detail *infra*, these actions in turn caused pharmacists to submit claims for reimbursement for Cephalon's drugs to Government Programs, including Medicare and Medicaid.

408. 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 analogs.

409. 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.

410. 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.

411. 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 analogs.

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

413. 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.

414. 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.

415. 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.

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

416. 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.

417. 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.

418. 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.

419. Cephalon promoted Provigil, Nuvigil 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.

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

421. As a result of physicians' prescribing of Cephalon's drugs, pharmacists filled prescriptions and submitted claims to Government Programs for payment of Cephalon's drugs for these uses.

422. 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 analogs.

423. Cephalon's off-label promotion of Provigil, Nuvigil and Fentora therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

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

425. 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.

426. 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.

1. Submission of False Claims to Medicaid

427. 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.

428. 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.

429. 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.

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

431. 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).

432. 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.

433. 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).

434. 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.

435. 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.

436. 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.

437. 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 D

438. 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.

439. 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.

440. 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.

441. 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.

C. Cephalon's False Certifications of Compliance with the Law Constituted Making of False Statements Material to False Claims

442. As a party to the Medicaid Rebate Agreement between the United States Secretary of Health and Human Services pursuant to the Social Security Act, 42 U.S.C. § 1396s, Cephalon (Labeler Code 00047), as well as various provider agreements, drug products are only eligible for reimbursement if and when Cephalon is in compliance with applicable federal and state laws.

443. These laws include, but are not limited to, the federal and corresponding state anti-kickback statutes, the FDMA, the Food, Drug & Cosmetic Act and all related regulations, and HIPAA.

444. As described in this Second Amended Complaint, Cephalon has knowingly and repeatedly violated these laws in the promotion of its drug products. These violations have not been incidental, but instead have been central to Cephalon's sales strategy.

445. Accordingly, Cephalon has, expressly and impliedly, falsely certified its compliance with these federal and state statutes and regulations.

446. Cephalon's certifications of compliance with these statutes and regulations were material to Government Programs' decisions to make reimbursements for Cephalon's drugs.

Had Government Programs known that Cephalon's certifications of compliance with the law were false, they would not have made reimbursements for its drugs.

447. Cephalon's false certifications of compliance with the law constituted the making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, and they directly caused Government Programs to pay or reimburse for prescriptions that were not eligible for payment or reimbursement.

448. Cephalon knew that its certifications of compliance with the law were false, and that its false certifications would cause Government Programs to make payments for its drugs.

D. Cephalon Conspired with Takeda Pharmaceutials North America, Inc. ("Takeda") to Defraud Government Programs

449. As alleged in this Second Amended Complaint, Cephalon conspired with Takeda to further the overall fraudulent marketing of Provigil by causing and training Takeda reps to engage in off-label promotion of Provigil as Cephalon's "co-promoter" during the same time Cephalon was under scrutiny (as seeking to avoid yet additional scrutiny) by the Government for its own scheme ("overt acts").

450. On June 12, 2006—well after the Government's investigation of Provigil had started—Cephalon and Takeda entered into a co-promotion agreement ("Agreement") under which (formally and in practice), and until the termination of the Agreement on November 1, 2008, (a) Cephalon economically benefitted from Takeda's sale of Cephalon's drug, with Cephalon paying royalties to Takeda; (b) Cephalon trained Takeda representatives to sell Provigil, including off-label in the same manner it had been doing; (c) Cephalon shared certain of its Provigil speakers (who, as discussed *infra*, were both rewarded for their own prescribing behavior by receiving speaking opportunities and who in turn encouraged other physicians to sell off-label) with Takeda, who then used the same speakers; and (d) notably, Cephalon dictated the

particular physicians that Takeda representatives were to call on, and conspired to have Takeda representatives call on the very physicians whom Cephalon knew were writing exclusively off-label.

451. The co-promotion agreement acknowledged itself that the "existing call plan of the Cephalon Provigil Sales Force Representatives" consisted "primarily of primary care physicians, psychiatrists and neurologists." *See, e.g.*, Co-Promotion Agreement at 1.11. Cephalon and Takeda conspired to ensure that, notwithstanding the fact that Cephalon was under the microscope of a federal investigation, it was business as usual for the off-label sales of Provigil because Takeda would continue the off-label promotion.

452. As a result of these overt acts pursuant to this conspiracy, Cephalon intentionally conspired with Takeda to get a false or fraudulent claim allowed or paid by the United States; and performed one or more overt acts to effect the object of the conspiracy; and Government Programs suffered damages as a result of the false or fraudulent claims.

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

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

454. 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).

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

[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).

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(B))[2]

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

457. 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).

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

459. As a result of Defendants' actions as set forth above in this 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]

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

461. As detailed above, Defendants knowingly conspired with Takeda Pharmaceuticals North America, Inc. to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2). Defendants and Takeda committed overt acts in furtherance of the conspiracy as described above.

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[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).

[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).

462. 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]

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

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

465. 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 California False Claims Act)

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

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

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 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).

[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).

469. 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).

470. 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).

471. 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.

472. 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 VI

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

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

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

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 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).

476. 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).

477. 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).

478. 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.

479. 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 VII
(Violation of Delaware False Claims and Reporting Act)

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

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

483. 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).

484. 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, § 120l(a)(7).

485. 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.

486. 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 VIII
(Violation of District of Columbia False Claims Act)

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

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

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 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).

490. 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).

491. 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).

492. 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.

493. 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 IX
(Violation of Florida False Claims Act)

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

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

497. 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).

498. 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).

499. 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.

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

COUNT X
(Violation of Georgia False Medicaid Claims Act)

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

502. This is a civil action brought by Relators, 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).

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 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).

504. 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).

505. 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).

506. 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.

507. 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 XI
(Violation of Hawaii False Claims Act)

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

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

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 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).

511. 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).

512. 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).

513. 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.

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

COUNT XII
(Violation of Illinois False Claims Act)

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

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

518. 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).

519. 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).

520. 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.

521. 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 XIII
(Violation of Indiana False Claims and Whistleblower Protection Act)

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

523. This is a civil action brought by Relators, 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).

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 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).

525. 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).

526. 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).

527. 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.

528. 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 XIV
(Violation of Louisiana Medical Assistance Programs Integrity Law)

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

530. This is a civil action brought by Relators, 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.

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 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).

532. 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).

533. 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).

534. 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.

535. 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 XV
(Violation of Massachusetts False Claims Act)

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

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

539. 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).

540. 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).

541. 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.

542. 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 XVI
(Violation of Michigan Medicaid False Claims Act)

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

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

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 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).

546. 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).

547. 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).

548. 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).

549. 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.

550. 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 XVII
(Violation of Montana False Claims Act)

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

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

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 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).

554. 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).

555. 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).

556. 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.

557. 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 XVIII
(Violation of Nevada False Claims Act)

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

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

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 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).

561. 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).

562. 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).

563. 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.

564. 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 XIX
(Violation of New Jersey False Claims Act)

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

566. This is a civil action brought by Relators, 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).

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 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).

568. 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).

569. 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).

570. 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.

571. 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.

572.

COUNT XX
(Violation of New York False Claims Act)

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

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

575. 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).

576. 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).

577. 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).

578. 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.

579. 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 XXI
(Violation of North Carolina False Claims Act)

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

581. This is a civil action brought by Relators, on behalf of the State of North Carolina, against Defendants under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).

582. 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).

583. 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).

584. 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).

585. 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.

586. 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 XXII
(Violation of Oklahoma Medicaid False Claims Act)

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

588. This is a civil action brought by Relators, 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).

589. 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).

590. 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).

591. 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).

592. 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.

593. 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 XXIII
(Violation of Rhode Island False Claims Act)

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

595. This is a civil action brought by Relators, 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).

596. 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).

597. 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).

598. 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).

599. 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.

600. 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 XXIV
(Violation of Tennessee Medicaid False Claims Act)

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

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

603. 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).

604. 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).

605. 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).

606. 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.

607. 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 XXV
(Violation of Texas Medicaid Fraud Prevention Act)

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

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

610. 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).

611. 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).

612. 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).

613. 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).

614. 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.

615. 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 XXVI
(Violation of Virginia Fraud Against Taxpayers Act)

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

617. This is a civil action brought by Relators, 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).

618. 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).

619. 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).

620. 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).

621. 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.

622. 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 XXVII
(Violation of Wisconsin False Claims for Medical Assistance Law)

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

624. 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).

625. 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).

626. 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).

627. 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.

628. 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 pray 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.*; 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.*; Mass. Gen. Laws ch. 12, § 5A *et*

seq.; Mich. Comp. Laws § 400.601 *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.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), 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, La. Rev. Stat. Ann. § 439.4, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, 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 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;

F. 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;

G. 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;

H. 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;

I. 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;

J. 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;

K. 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;

L. 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;

M. 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;

N. 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;

O. 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;

P. 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;

Q. 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;

R. 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;

S. 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;

T. 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;

U. 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;

V. 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;

W. 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;

X. 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;

Y. 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;

Z. 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;

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

BB. 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

CC. 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: February 28, 2014

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2014, I caused true and correct copies of the foregoing Second Amended Complaint be sent to the persons listed below via first-class mail, postage prepaid.

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